

US3412337 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3412337

Form: Participant Creation

Data signed: (b) (4) 18 Apr 2021 21:32:23

Generated On: 09 Jun 2021 17:31:32

Participant ID

US3412337

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

US3412337

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	71
Age Units	YEARS
Age (Derived)	71
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Date of Informed Consent (<i>dd MMM yyyy</i>)	31 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Condition	ALLERGIC RHINITIS SEASONAL
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Condition	COPD
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Condition	HYPERLIPIDEMIA
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)	

US3412337

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Start Year (derived)	1989
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	31 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:27 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 11:27
Height (<i>xxx.x</i>)	157.7 cm
Weight (<i>xxx.x</i>)	73.0 kg
BMI (<i>xxx.x</i>)	29.35347 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Date of assessment (dd MMM yyyy) 31 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 1989

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

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

PART-TIME AMUSEMENT /
THEME PARK

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 12:40:59

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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	True
Specify	PMH OF COPD

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

What was the date of randomization? (dd MMM yyyy) 31 AUG 2020

What was the participant's randomization number? 189119

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) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	11:27 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 11:27
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	12:30 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 12:30
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 11:55 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 11:55

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

31 AUG 2020

Collection time (00:00-23:59)

11:43 (24 HR)

Collection date and time (derived)

31 AUG 2020 11:43

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:35	31 AUG 2020 11:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

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

97.4 °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

31 AUG 2020 12:33

PC Open Date & Time

31 AUG 2020 12:15

PC Close Date & Time

31 AUG 2020 14:45

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

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	31 AUG 2020 20:07
PC Open Date & Time	31 AUG 2020 15:40
PC Close Date & Time	01 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:32

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

01 SEP 2020 20:23

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 19:58

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:32

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

97.4 °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

03 SEP 2020 20:28

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:32

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 20:09

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

05 SEP 2020 19:34

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

06 SEP 2020 20:05

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

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 ☐

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

5

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)**

3

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

31 AUG 2020 12:36

PC Open Date & Time

31 AUG 2020 12:15

PC Close Date & Time

31 AUG 2020 14:45

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

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

31 AUG 2020 20:07

PC Open Date & Time

31 AUG 2020 15:40

PC Close Date & Time

01 SEP 2020 11:59

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:32

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

01 SEP 2020 20:23

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:32

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

02 SEP 2020 19:59

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:32

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

03 SEP 2020 20:29

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:32

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

04 SEP 2020 20:10

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:32

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

05 SEP 2020 19:34

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:32

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

06 SEP 2020 20:05

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 12:37
PC Open Date & Time	31 AUG 2020 12:15
PC Close Date & Time	31 AUG 2020 14:45

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 20:08
PC Open Date & Time	31 AUG 2020 15:40
PC Close Date & Time	01 SEP 2020 11:59

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

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

49 of 2125

EAB) (1725)

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 20:24
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

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

51 of 2125

EAB) (1725)

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 19:59
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 2125

EAB) (1725)

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 20:29
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

55 of 2125

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 20:10
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

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

57 of 2125

EAB) (1725)

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 19:34
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

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

59 of 2125

EAB) (1725)

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 20:06
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3412337

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412337

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412337

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:40:58

Generated On: 09 Jun 2021 17:31:32

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3412337

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:40:58

Generated On: 09 Jun 2021 17:31:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412337

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412337

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412337

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	VISIT2

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

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)	28 SEP 2020
Time of assessment (00:00-23:59)	10:44 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 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)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	12:06 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 12:06
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3412337

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3412337

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

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) 28 SEP 2020

What was the treatment time? (00:00-23:59) 11:30 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 11:30

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

What was the frequency of the study treatment dosing? ONCE

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

US3412337

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

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

Collection date (dd MMM yyyy)	28 SEP 2020
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Collection time (00:00-23:59)	10:59 (24 HR)
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Collection date and time (derived)	28 SEP 2020 10:59
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US3412337

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:03	28 SEP 2020 11:03
Nasopharyngeal Swab 2	No		

US3412337

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

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

28 SEP 2020 12:12

PC Open Date & Time

28 SEP 2020 11:50

PC Close Date & Time

28 SEP 2020 14:20

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

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 99.6 °F

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

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

PC Time Stamp	28 SEP 2020 20:01
PC Open Date & Time	28 SEP 2020 15:15
PC Close Date & Time	29 SEP 2020 11:59

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:32

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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 19:31
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:32

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

97.4 °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

30 SEP 2020 19:32

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 19:35

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:32

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

96.7 °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

02 OCT 2020 19:21

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 19:28

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

04 OCT 2020 20:09

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

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

28 SEP 2020 12:13

PC Open Date & Time

28 SEP 2020 11:50

PC Close Date & Time

28 SEP 2020 14:20

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

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

28 SEP 2020 20:02

PC Open Date & Time

28 SEP 2020 15:15

PC Close Date & Time

29 SEP 2020 11:59

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:32

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

29 SEP 2020 19:31

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:32

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

30 SEP 2020 19:32

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:32

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

01 OCT 2020 19:36

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:32

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

02 OCT 2020 19:21

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:32

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

03 OCT 2020 19:28

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:32

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

04 OCT 2020 20:10

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 12:13
PC Open Date & Time	28 SEP 2020 11:50
PC Close Date & Time	28 SEP 2020 14:20

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 20:02
PC Open Date & Time	28 SEP 2020 15:15
PC Close Date & Time	29 SEP 2020 11:59

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

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 ☒

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 19:32
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

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

97 of 2125

EAB) (1725)

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 19:33
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

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 ☒

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 19:36
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 19:22
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

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

103 of 2125

EAB) (1725)

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 19:28
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

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 ☒

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 20:10
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3412337

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412337

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412337

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412337

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412337

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412337

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412337

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3412337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3412337

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

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.

US3412337

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 OCT 2020

Collection time (00:00-23:59)

10:15 (24 HR)

Collection date and time (derived)

26 OCT 2020 10:15

US3412337

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:40:59

Generated On: 09 Jun 2021 17:31:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

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

Date and time of submission

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 <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	07 NOV 2020 07:07:07
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 NOV 2020 08:59:25
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 09:13:56

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 <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	25 NOV 2020 06:51:33
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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	02 DEC 2020 08:10:28
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

09 DEC 2020 08:55:43

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

16 DEC 2020 09:22:48

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

23 DEC 2020 08:31:12

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 JAN 2021 19:38:30

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	06 JAN 2021 02:48:37
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

13 JAN 2021 07:12:23

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

20 JAN 2021 06:46:00

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

29 JAN 2021 12:01:28

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

03 FEB 2021 10:04:33

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

12 FEB 2021 11:49:41

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

17 FEB 2021 07:30:14

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 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	24 FEB 2021 08:09:06
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

03 MAR 2021 06:23:57

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 <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	10 MAR 2021 09:03:55
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

17 MAR 2021 07:42:29

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 08:42:08

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

02 APR 2021 15:50:12

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

07 APR 2021 10:18:01

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

14 APR 2021 07:34:11

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

21 APR 2021 07:39:33

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 <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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 <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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JUN 2021 00:01
Patient Cloud Close Date & Time	27 JUN 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2021 00:01
Patient Cloud Close Date & Time	04 JUL 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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="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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 369

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 390

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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°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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	24 OCT 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
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Patient Cloud Close Date & Time	14 NOV 2021 23:59
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US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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="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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
Patient Cloud Close Date & Time	21 NOV 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	05 DEC 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	12 DEC 2021 23:59
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US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	19 DEC 2021 23:59
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US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	26 DEC 2021 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
Patient Cloud Close Date & Time	09 JAN 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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°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 ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

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06 FEB 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 <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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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°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 ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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="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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	31 JUL 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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="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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
Patient Cloud Close Date & Time	21 AUG 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	28 AUG 2022 23:59
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US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	09 OCT 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 <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"/>

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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°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 ☐

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3412337

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:31:32

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		02 MAR 2021 10:20:23

US3412337

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:43:07

Generated On: 09 Jun 2021 17:31:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412337

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:43:07

Generated On: 09 Jun 2021 17:31:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412337

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:32:23

Generated On: 09 Jun 2021 17:31:32

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3412337

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:32:23

Generated On: 09 Jun 2021 17:31:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412337

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:32:23

Generated On: 09 Jun 2021 17:31:32

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3412337

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:32:23

Generated On: 09 Jun 2021 17:31:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412337

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:32:23

Generated On: 09 Jun 2021 17:31:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412337

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:32:23

Generated On: 09 Jun 2021 17:31:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412337

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:32:24

Generated On: 09 Jun 2021 17:31:32

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

Visit date (dd MMM yyyy)	29 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3412337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 21:32:24

Generated On: 09 Jun 2021 17:31:32

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3412337

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:32:24

Generated On: 09 Jun 2021 17:31:32

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.

US3412337

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:32:24

Generated On: 09 Jun 2021 17:31:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 MAR 2021

Collection time (00:00-23:59)

11:10 (24 HR)

Collection date and time (derived)

29 MAR 2021 11:10

US3412337

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:32:23

Generated On: 09 Jun 2021 17:31:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412337

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412337

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:31:32

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3412337

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

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:32:23

Generated On: 09 Jun 2021 17:31:32

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

Visit date (dd MMM yyyy)	5 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3412337

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

Form: Unblinding

Data signed: (b) (4) 18 Apr 2021 21:32:23

Generated On: 09 Jun 2021 17:31:32

Date of updated informed consent (dd MMM yyyy) 5 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) 5 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 _____

US3412337

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:32:23

Generated On: 09 Jun 2021 17:31:32

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

Collection date (dd MMM yyyy)	5 JAN 2021
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Collection time (00:00-23:59)	20:25 (24 HR)
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Collection date and time (derived)	5 JAN 2021 20:25
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US3412337

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 18 Apr 2021 21:32:23

Generated On: 09 Jun 2021 17:31:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 JAN 2021
Collection time (00:00 - 23:59)	10:28
Collection Date and Time (derived)	5 JAN 2021 10:28

US3412337

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:42:43

Generated On: 09 Jun 2021 17:31:32

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3412337

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

AEID	USA-US061-2021-MRNA-1273-P30 1000010
Adverse event	LEFT HIP FRACTURE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	22 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	25 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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US3412337

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

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	

US3412337

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

SUBJECT PRESENTED TO THE
ED AS A 72 Y/O FEMALE WITH
HISTORY OF COPD,
HYPERLIPIDEMIA, AND GERD.
SUBJECT HAD A FALL ON
22-FEB-21. RECEIVED BLINDED
MRNA-1273 ON 31-AUG-20 AND
08-SEP-20. INITIAL
PRESENTATION VITAL SIGNS
WERE SAO2 95%. PHYSICAL
EXAM SIGNIFICANT FOR L HIP
TTP. LABS H/H 15.4/45.5.
IMAGING: X-RAY L HIP
DETERMINED
INTERTROCHANTER L
FEMORAL NECK FRACTURE.
CXR SHOWED LARGE HIATAL
HERNIA AND L LUNG BASE
ATELECTASIS. NO NEW
FINDINGS. LEFT KNEE
X-RAY-WNL. COURSE OF
TREATMENT PROCEEDED WITH
SURGERY ON 23-FEB-21.
INTRAMEDULLARY NAIL
FIXATION FEMUR FRACTURE.
SUBJECT WAS DISCHARGED
WITH OXYCODONE PRN FOR
PAIN, XANELTO 10MG, QD, FOR
14 DAYS FOR DVT
PROPHYLAXIS, AND
MELATONIN 3MG PRN FOR
INSOMNIA. PER SUBJECT
THERE HAS BEEN NO
WORSENING. SUBJECT
PROGRESSED TO PT DURING

US3412337

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

HER HOSPITAL STAY AND WAS
DISCHARGED TO A REHAB
FACILITY ON 25-FEB-2021.
SUBJECT HAS BEEN RELEASED
AND HAS SINCE BEEN SEEN AT
OUR SITE ON 29-MAR-21. SHE
CONTINUES TO IMPROVE AND
SAE IS CONSIDERED CLOSED.
NO COVID SWAB
DOCUMENTED ACCORDING TO
MEDICAL RECORDS

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

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 14:46:17

Generated On: 09 Jun 2021 17:31:32

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

Yes ☒

No ☐

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

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HTN

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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EAB) (1725)

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US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

	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"/>

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

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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US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

	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 1975	
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"/>

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

Name of Medication PRAVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

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 ☐

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EAB) (1725)

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

	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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

Name of Medication TRAZADONE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

	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 2016	
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) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

Name of Medication ALBUTEROL INHALER

Prophylaxis Yes ☐
No ☒

Indication COPD

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

Name of Medication BEVESPI INHALER

Prophylaxis Yes ☐
No ☒

Indication COPD

Dose per administration 9/4.8

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

Name of Medication FIBER

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

	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"/>

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication SOLICITED INJECTION SITE
PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration 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) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

Name of Medication CLARITON -

Prophylaxis Yes ☐
No ☒

Indication ALLERGIC RHINITIS -
SEASONAL

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

	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)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH FLU
PREVENTION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" 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)	05 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

Name of Medication MIRALAX

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION PROPHYLACTIC

Dose per administration 17

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication HIP FRACTURE PAIN

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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EAB) (1725)

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

	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)	22 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication HIP FRACTURE PAIN

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 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)		29 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

Name of Medication SENNA-S

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION PROPHYLACTIC

Dose per administration 8.6/50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 FEB 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 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HIP FRACTURE PAIN

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

	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)		22 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

Name of Medication MELATONIN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 3

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 FEB 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"/>

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

Name of Medication XERALTO

Prophylaxis Yes ☒
No ☐

Indication DVT PROPHYLAXIS FROM SURGERY

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 14:44:49

Generated On: 09 Jun 2021 17:31:32

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3412337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Apr 2021 14:44:50

Generated On: 09 Jun 2021 17:31:32

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3412337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Apr 2021 13:33:16

Generated On: 09 Jun 2021 17:31:32

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
23 FEB 2021	INTRAMEDULLARY NAIL FIXATION FEMUR FRACTURE	Adverse Event	
23 FEB 2021	CHEST X-RAY	Adverse Event	
23 FEB 2021	X-RAY LEFT HIP	Adverse Event	

US3412337

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:31:32

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

US3412337

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:31:32

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 ☐

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 14:44:50

Generated On: 09 Jun 2021 17:31:32

SAEID	USA-US061-2021-MRNA-1273-P301000010
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 14:44:50

Generated On: 09 Jun 2021 17:31:32

SAEID	USA-US061-2021-MRNA-1273-P301000010
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	25/FEB/2021 11:25
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

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 14:44:50

Generated On: 09 Jun 2021 17:31:32

SAEID	USA-US061-2021-MRNA-1273-P301000010
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	15/APR/2021 12:19
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

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 14:44:50

Generated On: 09 Jun 2021 17:31:32

SAEID	USA-US061-2021-MRNA-1273-P301000010
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	22/APR/2021 10:35
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

US3412337 (Prod: New Horizons Clinical Research)

US3412337

Form: Participant Creation

Generated On: 09 Jun 2021 17:31:32

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered 'US3412337'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 15:04:52

US3412337

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User closed query 'Per CDM, Please complete all the applicable pages of this visit' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 05:36:01
Query 'Per CDM, Please complete all the applicable pages of this visit' answered with 'PER CDM ALL PAGES OF VISIT 1 COMPLETE' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	29 Sep 2020 17:45:22
User opened query 'Per CDM, Please complete all the applicable pages of this visit' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:56:38
User entered 'Yes (Y)'		31 Aug 2020 15:57:34

US3412337

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '31 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 15:04:53

US3412337

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:57:34

US3412337

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered 'SCRN'	System	31 Aug 2020 15:57:34

US3412337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:32

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered (b) (6) 1948'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 15:04:54

US3412337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:32

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '71'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:57:59

US3412337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:32

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered 'YEARS'	System	31 Aug 2020 15:57:59

US3412337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:32

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered '71'	System	31 Aug 2020 15:58:34

US3412337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:32

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:57:59

US3412337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:32

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:57:59

US3412337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:32

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:57:59

US3412337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:32

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:57:59

US3412337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:32

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:57:59

US3412337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:32

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:57:59

US3412337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:32

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:57:59

US3412337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:32

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:57:59

US3412337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:32

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:57:59

US3412337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:32

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:57:59

US3412337

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:32

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:57:59

US3412337

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:32

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:58:34

US3412337

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered 'Aug 2020'	System	31 Aug 2020 15:58:34

US3412337

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered '2020'	System	31 Aug 2020 15:58:34

US3412337

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:32

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Amendment 2 (2)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:58:34

US3412337

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:58:34

US3412337

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:58:34

US3412337

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:32

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:58:34

US3412337

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:32

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:58:34

US3412337

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:32

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 15:04:53

US3412337

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:32

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered 'I'	System	31 Aug 2020 15:58:43

US3412337

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:58:43

US3412337

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:31:32

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:28:06

US3412337

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:32:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:32:43
Data point term sent to Coder	System	10 Sep 2020 16:31:44
User entered 'ALLERGIC RHINITIS SEASONAL'	Mylene Asmar-Rios	10 Sep 2020 16:31:06
	(b) (4)	

US3412337

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:31:06

US3412337

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:31:06

US3412337

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:31:06

US3412337

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:31:06

US3412337

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:31:06

US3412337

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered 'Jan 2010'	System	10 Sep 2020 16:31:06

US3412337

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered '2010'	System	10 Sep 2020 16:31:06

US3412337

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered empty.	System	10 Sep 2020 16:31:06

US3412337

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered empty.	System	10 Sep 2020 16:31:06

US3412337

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:31:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:32:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:32:43
Data point term sent to Coder	System	10 Sep 2020 16:31:45
User entered 'COPD'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:31:21

US3412337

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'UN UNK 2014'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:31:21

US3412337

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:31:21

US3412337

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:31:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:31:21

US3412337

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:31:21

US3412337

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:31:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:31:21

US3412337

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered 'Jan 2014'	System	10 Sep 2020 16:31:21

US3412337

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered '2014'	System	10 Sep 2020 16:31:21

US3412337

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered empty.	System	10 Sep 2020 16:31:21

US3412337

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered empty.	System	10 Sep 2020 16:31:21

US3412337

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:31:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:32:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:32:43
Data point term sent to Coder	System	10 Sep 2020 16:31:45
User entered 'HYPERLIPIDEMIA'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:31:41

US3412337

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'UN UNK 2000'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:31:41

US3412337

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:31:41

US3412337

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:31:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:31:41

US3412337

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:31:41

US3412337

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:31:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:31:41

US3412337

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered 'Jan 2000'	System	10 Sep 2020 16:31:41

US3412337

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered '2000'	System	10 Sep 2020 16:31:41

US3412337

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered empty.	System	10 Sep 2020 16:31:41

US3412337

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered empty.	System	10 Sep 2020 16:31:41

US3412337

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:33:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:33:44
Data point term sent to Coder	System	10 Sep 2020 16:32:48
User entered 'HYPERTENSION'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:31:59

US3412337

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'UN UNK 2000'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:31:59

US3412337

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:31:59

US3412337

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:31:59

US3412337

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:31:59

US3412337

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:31:59

US3412337

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered 'Jan 2000'	System	10 Sep 2020 16:31:59

US3412337

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered '2000'	System	10 Sep 2020 16:31:59

US3412337

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered empty.	System	10 Sep 2020 16:31:59

US3412337

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered empty.	System	10 Sep 2020 16:31:59

US3412337

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:31:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
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.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 16:33:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:33:45
Data point term sent to Coder	System	10 Sep 2020 16:32:51
User entered 'GERD'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:32:40

US3412337

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'UN UNK 1975'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:32:40

US3412337

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:32:40

US3412337

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:31:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:32:40

US3412337

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:32:40

US3412337

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:31:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:32:40

US3412337

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered 'Jan 1975'	System	10 Sep 2020 16:32:40

US3412337

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered '1975'	System	10 Sep 2020 16:32:40

US3412337

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered empty.	System	10 Sep 2020 16:32:40

US3412337

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered empty.	System	10 Sep 2020 16:32:40

US3412337

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:31:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:34:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:34:44
Data point term sent to Coder	System	10 Sep 2020 16:33:53
User entered 'INSOMNIA'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:33:09

US3412337

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'UN UNK 2003'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:33:09

US3412337

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:33:09

US3412337

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:31:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:33:09

US3412337

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:33:09

US3412337

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:31:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:33:09

US3412337

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered 'Jan 2003'	System	10 Sep 2020 16:33:09

US3412337

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered '2003'	System	10 Sep 2020 16:33:09

US3412337

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered empty.	System	10 Sep 2020 16:33:09

US3412337

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered empty.	System	10 Sep 2020 16:33:09

US3412337

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:31:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:23:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:23:48
Data point term sent to Coder	System	08 Oct 2020 16:28:03
User entered 'post menopausal'	Jacob sekinger (b) (4)	08 Oct 2020 16:27:13
	(b) (4)	

US3412337

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'un UNK 1989'	Jacob sekinger (b) (4)	08 Oct 2020 16:27:13

US3412337

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	Jacob sekinger (b) (4)	08 Oct 2020 16:27:13

US3412337

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:31:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	08 Oct 2020 16:27:13

US3412337

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Jacob sekinger (b) (4)	08 Oct 2020 16:27:13

US3412337

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:31:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	Jacob sekinger (b) (4)	08 Oct 2020 16:27:13

US3412337

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered 'Jan 1989'	System	08 Oct 2020 16:27:13

US3412337

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered '1989'	System	08 Oct 2020 16:27:13

US3412337

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered empty.	System	08 Oct 2020 16:27:13

US3412337

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered empty.	System	08 Oct 2020 16:27:13

US3412337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:35:32

US3412337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '31 Aug 2020'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:35:32

US3412337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '11:27'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:35:32

US3412337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered '31 Aug 2020 11:27'	System	10 Sep 2020 16:35:32

US3412337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '157.7' cm	(b) (4) Mylene Asmar-Rios	10 Sep 2020 16:35:32
DataPoint set to visible.	(b) (4) System	31 Aug 2020 15:58:43

US3412337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '73.0' kg	(b) (4) Mylene Asmar-Rios	10 Sep 2020 16:35:32
DataPoint set to visible.	(b) (4) System	31 Aug 2020 15:58:43

US3412337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered '29.35347'	System	10 Sep 2020 16:35:32
DataPoint set to visible.	System	31 Aug 2020 15:58:43

US3412337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered 'kg/m2'	System	10 Sep 2020 16:35:32
DataPoint set to visible.	System	31 Aug 2020 15:58:43

US3412337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:35:32

US3412337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:35:32

US3412337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:35:32

US3412337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:35:32

US3412337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered 'bpm'	System	10 Sep 2020 16:35:32

US3412337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:35:32

US3412337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered 'breaths/min'	System	10 Sep 2020 16:35:32

US3412337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:35:32

US3412337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered 'mmHg'	System	10 Sep 2020 16:35:32

US3412337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:35:32

US3412337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered 'mmHg'	System	10 Sep 2020 16:35:32

US3412337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13

US3412337

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13

US3412337

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:32

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	(b) (4)	10 Sep 2020 16:36:39
User entered 'Yes (Y)' reason for change: Data Entry Error	System	10 Sep 2020 16:36:39
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	Mylene Asmar-Rios	10 Sep 2020 16:36:39
User entered 'No (N)'	(b) (4)	10 Sep 2020 16:35:47
	System	10 Sep 2020 16:35:47
	Mylene Asmar-Rios	10 Sep 2020 16:35:47
	(b) (4)	

US3412337

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '31 Aug 2020'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:35:47

US3412337

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:31:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '31 Aug 2020'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:38:24

US3412337

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:38:24

US3412337

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:31:32

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 06:42:31
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'updated. ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	08 Oct 2020 16:26:37
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 06:15:41
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:38:24

US3412337

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:31:32

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:38:24

US3412337

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:38:24

US3412337

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:31:32

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:38:24

US3412337

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'UN UNK 1989'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:38:24

US3412337

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:31:32

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:38:24

US3412337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:46:17

US3412337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:46:17

US3412337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:32

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)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:46:17

US3412337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:32

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)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:46:17

US3412337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:46:17

US3412337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:32

[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)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:46:17

US3412337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:32

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)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:46:17

US3412337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:32

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)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:46:17

US3412337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:32

[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)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:46:17

US3412337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:32

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)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:46:17

US3412337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:32

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)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:46:17

US3412337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:32

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	29 Sep 2020 17:44:25
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:46:17

US3412337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:32

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'PART-TIME AMUSEMENT / THEME PARK' reason for change: Data Entry Error	Melissa Fuson (b) (4)	29 Sep 2020 17:44:25
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:46:17

US3412337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:32

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:46:17

US3412337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:46:17

US3412337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:32

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)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:46:17

US3412337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:32

[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)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:46:17

US3412337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:32

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)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '0'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:46:17

US3412337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'I'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:46:17

US3412337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:32

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	29 Sep 2020 17:44:25
User entered '0'	(b) (4)	
	Mylene Asmar-Rios	10 Sep 2020 16:46:17
	(b) (4)	

US3412337

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:32

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'PMH OF COPD' reason for change:	(b) (4)	
Data Entry Error	Melissa Fuson (b) (4)	29 Sep 2020 17:44:25
User entered empty.	(b) (4)	
	Mylene Asmar-Rios	10 Sep 2020 16:46:17
	(b) (4)	

US3412337

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:56:07

US3412337

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:56:07

US3412337

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:56:07

US3412337

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'VISIT1'	System	31 Aug 2020 15:56:07

US3412337

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '31 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 15:54:17

US3412337

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:32

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '189119'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 15:54:17

US3412337

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 15:54:17

US3412337

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:32

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)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 13:25:22
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'YES' (Site from DM).	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:43:56
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:43:43
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 17:12:54

US3412337

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:32

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)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:43:43

US3412337

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:43:43

US3412337

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:32

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:43:43

US3412337

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:32

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:43:43

US3412337

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'No (N)'	Melissa Fuson (b) (4)	29 Sep 2020 17:46:38
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:50:04
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:42:36

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:32

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:32

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User accepted default value 'Pre-Dose (PREDOSE)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '31 Aug 2020'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '11:27'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered '31 Aug 2020 11:27'	System	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '36.9' C reason for change: Data Entry Error	Melissa Fuson (b) (4)	29 Sep 2020 17:47:31
User entered '98.5' F	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Oral (Oral)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '90'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'bpm'	System	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '18'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'breaths/min'	System	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '128'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'mmHg'	System	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '82'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'mmHg'	System	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:32

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User accepted default value 'Post-Dose (POSTDOSE)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '31 Aug 2020'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '12:30'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered '31 Aug 2020 12:30'	System	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '97.4' F	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Oral (Oral)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '62'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'bpm'	System	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '20'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'breaths/min'	System	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '124'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'mmHg'	System	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '76'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'mmHg'	System	10 Sep 2020 16:52:21

US3412337

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:29

US3412337

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:52:29

US3412337

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:59:24

US3412337

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:32

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:59:24

US3412337

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:32

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)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:59:24

US3412337

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:32

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 15:59:24

US3412337

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:59:24

US3412337

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '11:55'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:59:24

US3412337

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered '31 Aug 2020 11:55'	System	31 Aug 2020 15:59:24

US3412337

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:59:24

US3412337

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:32

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'ONCE'	System	31 Aug 2020 15:59:24

US3412337

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 15:59:24

US3412337

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:07:36

US3412337

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '31 Aug 2020'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:07:36

US3412337

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '11:43'	Mylene Asmar-Rios	10 Sep 2020 17:07:36

US3412337

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered '31 Aug 2020 11:43'	System	10 Sep 2020 17:07:36

US3412337

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:31:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '31 Aug 2020'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:08:02

US3412337

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:08:02

US3412337

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:08:02

US3412337

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '11:35'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:08:02

US3412337

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:32

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered '31 Aug 2020 11:35'	System	10 Sep 2020 17:08:02

US3412337

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:08:02

US3412337

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:08:02

US3412337

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:08:02

US3412337

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered empty.	System	10 Sep 2020 17:08:02

US3412337

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:01:48

US3412337

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'I'	System	08 Sep 2020 18:01:48

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T12:16:57', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '924bdc7f-a111-46f9-8c79-8ee71b3d8cf3'	System	31 Aug 2020 16:35:50
User entered 'Yes (Y)'	System	31 Aug 2020 16:35:50

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T12:33:45', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '924bdc7f-a111-46f9-8c79-8ee71b3d8cf3'	System	31 Aug 2020 16:35:50
User entered '97.4'	System	31 Aug 2020 16:35:50

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T12:33:51', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '924bdc7f-a111-46f9-8c79-8ee71b3d8cf3'	System	31 Aug 2020 16:35:50
User entered 'No (N)'	System	31 Aug 2020 16:35:50

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T12:33:59', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '924bdc7f-a111-46f9-8c79-8ee71b3d8cf3'	System	31 Aug 2020 16:35:50
User entered '31 Aug 2020 12:33'	System	31 Aug 2020 16:35:50

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '31 Aug 2020 12:15'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '31 Aug 2020 14:45'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T20:06:46', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '2cb620de-e253-4fff-ae29-00c73155441e'	System	01 Sep 2020 00:07:19
User entered 'Yes (Y)'	System	01 Sep 2020 00:07:19

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T20:07:05', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '2cb620de-e253-4fff-ae29-00c73155441e' User entered '97.4'	System	01 Sep 2020 00:07:19
	System	01 Sep 2020 00:07:19

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T20:07:09', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '2cb620de-e253-4fff-ae29-00c73155441e'	System	01 Sep 2020 00:07:19
User entered 'No (N)'	System	01 Sep 2020 00:07:19

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T20:07:16', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '2cb620de-e253-4fff-ae29-00c73155441e'	System	01 Sep 2020 00:07:19
User entered '31 Aug 2020 20:07'	System	01 Sep 2020 00:07:19

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '31 Aug 2020 15:40'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 2'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-01T20:22:31', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'b39d421a-cbca-43c1-b538-4204562abc52'	System	02 Sep 2020 00:23:05
User entered 'Yes (Y)'	System	02 Sep 2020 00:23:05

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-01T20:22:54', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'b39d421a-cbca-43c1-b538-4204562abc52'	System	02 Sep 2020 00:23:05
User entered '97.7'	System	02 Sep 2020 00:23:05

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-01T20:22:57', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'b39d421a-cbca-43c1-b538-4204562abc52'	System	02 Sep 2020 00:23:05
User entered 'No (N)'	System	02 Sep 2020 00:23:05

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-01T20:23:02', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'b39d421a-cbca-43c1-b538-4204562abc52'	System	02 Sep 2020 00:23:05
User entered '01 Sep 2020 20:23'	System	02 Sep 2020 00:23:05

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 3'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-02T19:58:25', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f1e996f8-dfbb-45c5-b560-960c99892d6f' User entered 'Yes (Y)'	System	02 Sep 2020 23:58:51
	System	02 Sep 2020 23:58:51

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-02T19:58:40', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f1e996f8-dfbb-45c5-b560-960c99892d6f' User entered '98.5'	System	02 Sep 2020 23:58:51
	System	02 Sep 2020 23:58:51

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-02T19:58:44', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f1e996f8-dfbb-45c5-b560-960c99892d6f'	System	02 Sep 2020 23:58:51
User entered 'No (N)'	System	02 Sep 2020 23:58:51

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-02T19:58:49', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f1e996f8-dfbb-45c5-b560-960c99892d6f'	System	02 Sep 2020 23:58:51
User entered '02 Sep 2020 19:58'	System	02 Sep 2020 23:58:51

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 4'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-03T20:28:23', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '43777fc3-9203-4e3b-878b-293e8d606f2e'	System	04 Sep 2020 00:28:43
User entered 'Yes (Y)'	System	04 Sep 2020 00:28:43

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-03T20:28:34', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '43777fc3-9203-4e3b-878b-293e8d606f2e'	System	04 Sep 2020 00:28:43
User entered '97.4'	System	04 Sep 2020 00:28:43

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-03T20:28:37', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '43777fc3-9203-4e3b-878b-293e8d606f2e'	System	04 Sep 2020 00:28:43
User entered 'No (N)'	System	04 Sep 2020 00:28:43

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-03T20:28:41', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '43777fc3-9203-4e3b-878b-293e8d606f2e'	System	04 Sep 2020 00:28:43
User entered '03 Sep 2020 20:28'	System	04 Sep 2020 00:28:43

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 5'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-04T20:09:32', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '38833831-2e16-43f2-a21d-1de21b4bf26c'	System	05 Sep 2020 00:09:49
User entered 'Yes (Y)'	System	05 Sep 2020 00:09:49

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-04T20:09:38', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '38833831-2e16-43f2-a21d-1de21b4bf26c'	System	05 Sep 2020 00:09:49
User entered '97.0'	System	05 Sep 2020 00:09:49

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-04T20:09:41', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '38833831-2e16-43f2-a21d-1de21b4bf26c'	System	05 Sep 2020 00:09:49
User entered 'No (N)'	System	05 Sep 2020 00:09:49

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-04T20:09:44', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '38833831-2e16-43f2-a21d-1de21b4bf26c'	System	05 Sep 2020 00:09:49
User entered '04 Sep 2020 20:09'	System	05 Sep 2020 00:09:49

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 6'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-05T19:34:07', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'e0a83a02-6f45-4e33-95f3-43d99b5aa343'	System	05 Sep 2020 23:34:22
User entered 'Yes (Y)'	System	05 Sep 2020 23:34:22

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-05T19:34:13', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'e0a83a02-6f45-4e33-95f3-43d99b5aa343'	System	05 Sep 2020 23:34:22
User entered '97.4'	System	05 Sep 2020 23:34:22

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-05T19:34:16', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'e0a83a02-6f45-4e33-95f3-43d99b5aa343'	System	05 Sep 2020 23:34:22
User entered 'No (N)'	System	05 Sep 2020 23:34:22

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-05T19:34:19', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'e0a83a02-6f45-4e33-95f3-43d99b5aa343'	System	05 Sep 2020 23:34:22
User entered '05 Sep 2020 19:34'	System	05 Sep 2020 23:34:22

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 7'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-06T20:05:06', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'dcb74756-3939-4204-a3dc-67a81df4f38e'	System	07 Sep 2020 00:05:24
User entered 'Yes (Y)'	System	07 Sep 2020 00:05:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-06T20:05:14', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'dcb74756-3939-4204-a3dc-67a81df4f38e'	System	07 Sep 2020 00:05:24
User entered '97.4'	System	07 Sep 2020 00:05:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-06T20:05:17', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'dcb74756-3939-4204-a3dc-67a81df4f38e'	System	07 Sep 2020 00:05:24
User entered 'No (N)'	System	07 Sep 2020 00:05:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-06T20:05:20', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'dcb74756-3939-4204-a3dc-67a81df4f38e'	System	07 Sep 2020 00:05:24
User entered '06 Sep 2020 20:05'	System	07 Sep 2020 00:05:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T12:35:44', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'c2c9efd5-8fd3-40f2-a8e8-87a7e71d92cd'	System	31 Aug 2020 16:36:29
User entered 'None (1)'	System	31 Aug 2020 16:36:29

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T12:35:48', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'c2c9efd5-8fd3-40f2-a8e8-87a7e71d92cd'	System	31 Aug 2020 16:36:29
User entered 'Yes (Y)'	System	31 Aug 2020 16:36:29

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T12:36:00', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'c2c9efd5-8fd3-40f2-a8e8-87a7e71d92cd'	System	31 Aug 2020 16:36:29
User entered '5'	System	31 Aug 2020 16:36:29

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T12:36:04', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'c2c9efd5-8fd3-40f2-a8e8-87a7e71d92cd'	System	31 Aug 2020 16:36:29
User entered 'Yes (Y)'	System	31 Aug 2020 16:36:29

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T12:36:08', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'c2c9efd5-8fd3-40f2-a8e8-87a7e71d92cd'	System	31 Aug 2020 16:36:29
User entered '3'	System	31 Aug 2020 16:36:29

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T12:36:12', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'c2c9efd5-8fd3-40f2-a8e8-87a7e71d92cd'	System	31 Aug 2020 16:36:29
User entered 'None (1)'	System	31 Aug 2020 16:36:29

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T12:36:22', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'c2c9efd5-8fd3-40f2-a8e8-87a7e71d92cd'	System	31 Aug 2020 16:36:29
User entered '31 Aug 2020 12:36'	System	31 Aug 2020 16:36:29

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '31 Aug 2020 12:15'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '31 Aug 2020 14:45'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T20:07:25', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '08cd5fa2-4912-49e7-af89-6f246851b78d'	System	01 Sep 2020 00:08:00
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 00:08:00

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T20:07:28', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '08cd5fa2-4912-49e7-af89-6f246851b78d'	System	01 Sep 2020 00:08:00
User entered 'No (N)'	System	01 Sep 2020 00:08:00

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T20:07:47', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '08cd5fa2-4912-49e7-af89-6f246851b78d'	System	01 Sep 2020 00:08:00
User entered 'No (N)'	System	01 Sep 2020 00:08:00

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T20:07:52', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '08cd5fa2-4912-49e7-af89-6f246851b78d'	System	01 Sep 2020 00:08:00
User entered 'None (1)'	System	01 Sep 2020 00:08:00

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T20:07:56', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '08cd5fa2-4912-49e7-af89-6f246851b78d'	System	01 Sep 2020 00:08:00
User entered '31 Aug 2020 20:07'	System	01 Sep 2020 00:08:00

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '31 Aug 2020 15:40'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 2'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-01T20:23:11', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f5903b5f-7e43-4974-b038-dda9841d7f01'	System	02 Sep 2020 00:23:42
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 00:23:42

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-01T20:23:14', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f5903b5f-7e43-4974-b038-dda9841d7f01'	System	02 Sep 2020 00:23:42
User entered 'No (N)'	System	02 Sep 2020 00:23:42

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-01T20:23:20', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f5903b5f-7e43-4974-b038-dda9841d7f01'	System	02 Sep 2020 00:23:42
User entered 'No (N)'	System	02 Sep 2020 00:23:42

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-01T20:23:30', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f5903b5f-7e43-4974-b038-dda9841d7f01'	System	02 Sep 2020 00:23:42
User entered 'None (1)'	System	02 Sep 2020 00:23:42

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-01T20:23:38', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f5903b5f-7e43-4974-b038-dda9841d7f01'	System	02 Sep 2020 00:23:42
User entered '01 Sep 2020 20:23'	System	02 Sep 2020 00:23:42

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 3'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-02T19:58:55', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'a983d003-97e9-462f-bb25-42b6348679d6'	System	02 Sep 2020 23:59:35
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 23:59:35

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-02T19:58:58', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'a983d003-97e9-462f-bb25-42b6348679d6'	System	02 Sep 2020 23:59:35
User entered 'No (N)'	System	02 Sep 2020 23:59:35

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-02T19:59:24', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'a983d003-97e9-462f-bb25-42b6348679d6'	System	02 Sep 2020 23:59:35
User entered 'No (N)'	System	02 Sep 2020 23:59:35

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-02T19:59:28', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'a983d003-97e9-462f-bb25-42b6348679d6'	System	02 Sep 2020 23:59:35
User entered 'None (1)'	System	02 Sep 2020 23:59:35

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-02T19:59:31', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'a983d003-97e9-462f-bb25-42b6348679d6'	System	02 Sep 2020 23:59:35
User entered '02 Sep 2020 19:59'	System	02 Sep 2020 23:59:35

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 4'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-03T20:28:51', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f523d8cb-41e0-438b-9adb-47627abb1c93'	System	04 Sep 2020 00:29:08
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 00:29:08

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-03T20:28:54', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f523d8cb-41e0-438b-9adb-47627abb1c93'	System	04 Sep 2020 00:29:08
User entered 'No (N)'	System	04 Sep 2020 00:29:08

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-03T20:28:57', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f523d8cb-41e0-438b-9adb-47627abb1c93'	System	04 Sep 2020 00:29:08
User entered 'No (N)'	System	04 Sep 2020 00:29:08

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-03T20:29:00', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f523d8cb-41e0-438b-9adb-47627abb1c93'	System	04 Sep 2020 00:29:08
User entered 'None (1)'	System	04 Sep 2020 00:29:08

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-03T20:29:04', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f523d8cb-41e0-438b-9adb-47627abb1c93'	System	04 Sep 2020 00:29:08
User entered '03 Sep 2020 20:29'	System	04 Sep 2020 00:29:08

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 5'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-04T20:09:52', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '4d4c05db-3c81-44eb-a660-dda513db4443'	System	05 Sep 2020 00:10:06
User entered 'None (1)'	System	05 Sep 2020 00:10:06

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-04T20:09:55', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '4d4c05db-3c81-44eb-a660-dda513db4443'	System	05 Sep 2020 00:10:06
User entered 'No (N)'	System	05 Sep 2020 00:10:06

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-04T20:09:57', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '4d4c05db-3c81-44eb-a660-dda513db4443'	System	05 Sep 2020 00:10:06
User entered 'No (N)'	System	05 Sep 2020 00:10:06

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-04T20:09:59', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '4d4c05db-3c81-44eb-a660-dda513db4443'	System	05 Sep 2020 00:10:06
User entered 'None (1)'	System	05 Sep 2020 00:10:06

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-04T20:10:02', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '4d4c05db-3c81-44eb-a660-dda513db4443'	System	05 Sep 2020 00:10:06
User entered '04 Sep 2020 20:10'	System	05 Sep 2020 00:10:06

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 6'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-05T19:34:24', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '263d2afb-139d-41e0-92ef-bf625987a642'	System	05 Sep 2020 23:34:35
User entered 'None (1)'	System	05 Sep 2020 23:34:35

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-05T19:34:26', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '263d2afb-139d-41e0-92ef-bf625987a642'	System	05 Sep 2020 23:34:35
User entered 'No (N)'	System	05 Sep 2020 23:34:35

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-05T19:34:27', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '263d2afb-139d-41e0-92ef-bf625987a642'	System	05 Sep 2020 23:34:35
User entered 'No (N)'	System	05 Sep 2020 23:34:35

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-05T19:34:29', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '263d2afb-139d-41e0-92ef-bf625987a642'	System	05 Sep 2020 23:34:35
User entered 'None (1)'	System	05 Sep 2020 23:34:35

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-05T19:34:32', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '263d2afb-139d-41e0-92ef-bf625987a642'	System	05 Sep 2020 23:34:35
User entered '05 Sep 2020 19:34'	System	05 Sep 2020 23:34:35

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 7'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-06T20:05:31', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'a078bd8a-e07d-4b2c-afb6-419c04dfa731'	System	07 Sep 2020 00:05:44
User entered 'None (1)'	System	07 Sep 2020 00:05:44

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-06T20:05:33', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'a078bd8a-e07d-4b2c-afb6-419c04dfa731'	System	07 Sep 2020 00:05:44
User entered 'No (N)'	System	07 Sep 2020 00:05:44

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-06T20:05:35', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'a078bd8a-e07d-4b2c-afb6-419c04dfa731'	System	07 Sep 2020 00:05:44
User entered 'No (N)'	System	07 Sep 2020 00:05:44

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-06T20:05:37', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'a078bd8a-e07d-4b2c-afb6-419c04dfa731'	System	07 Sep 2020 00:05:44
User entered 'None (1)'	System	07 Sep 2020 00:05:44

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-06T20:05:40', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'a078bd8a-e07d-4b2c-afb6-419c04dfa731'	System	07 Sep 2020 00:05:44
User entered '06 Sep 2020 20:05'	System	07 Sep 2020 00:05:44

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T12:36:59', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '66d1004a-3eed-4cd4-ba35-a657b61bf91f'	System	31 Aug 2020 16:37:28
User entered 'None (0)'	System	31 Aug 2020 16:37:28

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T12:37:03', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '66d1004a-3eed-4cd4-ba35-a657b61bf91f'	System	31 Aug 2020 16:37:28
User entered 'None (0)'	System	31 Aug 2020 16:37:28

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T12:37:06', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '66d1004a-3eed-4cd4-ba35-a657b61bf91f'	System	31 Aug 2020 16:37:28
User entered 'None (0)'	System	31 Aug 2020 16:37:28

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T12:37:09', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '66d1004a-3eed-4cd4-ba35-a657b61bf91f'	System	31 Aug 2020 16:37:28
User entered 'None (0)'	System	31 Aug 2020 16:37:28

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T12:37:12', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '66d1004a-3eed-4cd4-ba35-a657b61bf91f'	System	31 Aug 2020 16:37:28
User entered 'None (0)'	System	31 Aug 2020 16:37:28

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T12:37:14', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '66d1004a-3eed-4cd4-ba35-a657b61bf91f'	System	31 Aug 2020 16:37:28
User entered 'None (0)'	System	31 Aug 2020 16:37:28

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T12:37:18', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '66d1004a-3eed-4cd4-ba35-a657b61bf91f'	System	31 Aug 2020 16:37:28
User entered 'No (N)'	System	31 Aug 2020 16:37:28

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T12:37:24', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '66d1004a-3eed-4cd4-ba35-a657b61bf91f'	System	31 Aug 2020 16:37:28
User entered '31 Aug 2020 12:37'	System	31 Aug 2020 16:37:28

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '31 Aug 2020 12:15'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '31 Aug 2020 14:45'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T20:08:02', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '7d27c320-a8bd-4fc5-b406-2cef8be171c9'	System	01 Sep 2020 00:08:34
User entered 'None (0)'	System	01 Sep 2020 00:08:34

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T20:08:06', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '7d27c320-a8bd-4fc5-b406-2cef8be171c9'	System	01 Sep 2020 00:08:34
User entered 'None (0)'	System	01 Sep 2020 00:08:34

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T20:08:12', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '7d27c320-a8bd-4fc5-b406-2cef8be171c9'	System	01 Sep 2020 00:08:34
User entered 'None (0)'	System	01 Sep 2020 00:08:34

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T20:08:15', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '7d27c320-a8bd-4fc5-b406-2cef8be171c9'	System	01 Sep 2020 00:08:34
User entered 'None (0)'	System	01 Sep 2020 00:08:34

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T20:08:19', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '7d27c320-a8bd-4fc5-b406-2cef8be171c9'	System	01 Sep 2020 00:08:34
User entered 'None (0)'	System	01 Sep 2020 00:08:34

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T20:08:23', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '7d27c320-a8bd-4fc5-b406-2cef8be171c9'	System	01 Sep 2020 00:08:34
User entered 'None (0)'	System	01 Sep 2020 00:08:34

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T20:08:27', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '7d27c320-a8bd-4fc5-b406-2cef8be171c9'	System	01 Sep 2020 00:08:34
User entered 'No (N)'	System	01 Sep 2020 00:08:34

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-08-31T20:08:30', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '7d27c320-a8bd-4fc5-b406-2cef8be171c9'	System	01 Sep 2020 00:08:34
User entered '31 Aug 2020 20:08'	System	01 Sep 2020 00:08:34

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '31 Aug 2020 15:40'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 2'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-01T20:23:44', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '24392dd3-3304-4b17-b169-d38dca69e5e2'	System	02 Sep 2020 00:24:11
User entered 'None (0)'	System	02 Sep 2020 00:24:11

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-01T20:23:46', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '24392dd3-3304-4b17-b169-d38dca69e5e2'	System	02 Sep 2020 00:24:11
User entered 'None (0)'	System	02 Sep 2020 00:24:11

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-01T20:23:50', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '24392dd3-3304-4b17-b169-d38dca69e5e2'	System	02 Sep 2020 00:24:11
User entered 'None (0)'	System	02 Sep 2020 00:24:11

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-01T20:23:55', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '24392dd3-3304-4b17-b169-d38dca69e5e2'	System	02 Sep 2020 00:24:11
User entered 'None (0)'	System	02 Sep 2020 00:24:11

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-01T20:23:58', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '24392dd3-3304-4b17-b169-d38dca69e5e2'	System	02 Sep 2020 00:24:11
User entered 'None (0)'	System	02 Sep 2020 00:24:11

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-01T20:24:00', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '24392dd3-3304-4b17-b169-d38dca69e5e2'	System	02 Sep 2020 00:24:11
User entered 'None (0)'	System	02 Sep 2020 00:24:11

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-01T20:24:04', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '24392dd3-3304-4b17-b169-d38dca69e5e2'	System	02 Sep 2020 00:24:11
User entered 'No (N)'	System	02 Sep 2020 00:24:11

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-01T20:24:07', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '24392dd3-3304-4b17-b169-d38dca69e5e2'	System	02 Sep 2020 00:24:11
User entered '01 Sep 2020 20:24'	System	02 Sep 2020 00:24:11

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 3'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-02T19:59:36', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '9eaf4545-b6e5-4cbb-9dfb-5fb94c8e93dd'	System	02 Sep 2020 23:59:58
User entered 'None (0)'	System	02 Sep 2020 23:59:58

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-02T19:59:39', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '9eaf4545-b6e5-4cbb-9dfb-5fb94c8e93dd'	System	02 Sep 2020 23:59:58
User entered 'None (0)'	System	02 Sep 2020 23:59:58

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-02T19:59:41', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '9eaf4545-b6e5-4cbb-9dfb-5fb94c8e93dd'	System	02 Sep 2020 23:59:58
User entered 'None (0)'	System	02 Sep 2020 23:59:58

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-02T19:59:43', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '9eaf4545-b6e5-4cbb-9dfb-5fb94c8e93dd'	System	02 Sep 2020 23:59:58
User entered 'None (0)'	System	02 Sep 2020 23:59:58

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-02T19:59:45', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '9eaf4545-b6e5-4cbb-9dfb-5fb94c8e93dd'	System	02 Sep 2020 23:59:58
User entered 'None (0)'	System	02 Sep 2020 23:59:58

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-02T19:59:46', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '9eaf4545-b6e5-4cbb-9dfb-5fb94c8e93dd'	System	02 Sep 2020 23:59:58
User entered 'None (0)'	System	02 Sep 2020 23:59:58

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-02T19:59:49', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '9eaf4545-b6e5-4cbb-9dfb-5fb94c8e93dd'	System	02 Sep 2020 23:59:58
User entered 'No (N)'	System	02 Sep 2020 23:59:58

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-02T19:59:52', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '9eaf4545-b6e5-4cbb-9dfb-5fb94c8e93dd'	System	02 Sep 2020 23:59:58
User entered '02 Sep 2020 19:59'	System	02 Sep 2020 23:59:58

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 4'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-03T20:29:09', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '1054f505-7e8b-446a-a325-f9f2327c3b34'	System	04 Sep 2020 00:29:29
User entered 'None (0)'	System	04 Sep 2020 00:29:29

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-03T20:29:11', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '1054f505-7e8b-446a-a325-f9f2327c3b34'	System	04 Sep 2020 00:29:29
User entered 'None (0)'	System	04 Sep 2020 00:29:29

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-03T20:29:13', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '1054f505-7e8b-446a-a325-f9f2327c3b34'	System	04 Sep 2020 00:29:29
User entered 'None (0)'	System	04 Sep 2020 00:29:29

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-03T20:29:16', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '1054f505-7e8b-446a-a325-f9f2327c3b34'	System	04 Sep 2020 00:29:29
User entered 'None (0)'	System	04 Sep 2020 00:29:29

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-03T20:29:18', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '1054f505-7e8b-446a-a325-f9f2327c3b34'	System	04 Sep 2020 00:29:29
User entered 'None (0)'	System	04 Sep 2020 00:29:29

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-03T20:29:19', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '1054f505-7e8b-446a-a325-f9f2327c3b34'	System	04 Sep 2020 00:29:29
User entered 'None (0)'	System	04 Sep 2020 00:29:29

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-03T20:29:22', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '1054f505-7e8b-446a-a325-f9f2327c3b34'	System	04 Sep 2020 00:29:29
User entered 'No (N)'	System	04 Sep 2020 00:29:29

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-03T20:29:25', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '1054f505-7e8b-446a-a325-f9f2327c3b34'	System	04 Sep 2020 00:29:29
User entered '03 Sep 2020 20:29'	System	04 Sep 2020 00:29:29

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 5'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-04T20:10:06', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '8a6c77a2-4f11-4a25-98a7-8955d340ad02'	System	05 Sep 2020 00:10:24
User entered 'None (0)'	System	05 Sep 2020 00:10:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-04T20:10:08', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '8a6c77a2-4f11-4a25-98a7-8955d340ad02'	System	05 Sep 2020 00:10:24
User entered 'None (0)'	System	05 Sep 2020 00:10:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-04T20:10:10', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '8a6c77a2-4f11-4a25-98a7-8955d340ad02'	System	05 Sep 2020 00:10:24
User entered 'None (0)'	System	05 Sep 2020 00:10:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-04T20:10:11', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '8a6c77a2-4f11-4a25-98a7-8955d340ad02'	System	05 Sep 2020 00:10:24
User entered 'None (0)'	System	05 Sep 2020 00:10:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-04T20:10:13', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '8a6c77a2-4f11-4a25-98a7-8955d340ad02'	System	05 Sep 2020 00:10:24
User entered 'None (0)'	System	05 Sep 2020 00:10:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-04T20:10:15', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '8a6c77a2-4f11-4a25-98a7-8955d340ad02'	System	05 Sep 2020 00:10:24
User entered 'None (0)'	System	05 Sep 2020 00:10:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-04T20:10:17', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '8a6c77a2-4f11-4a25-98a7-8955d340ad02'	System	05 Sep 2020 00:10:24
User entered 'No (N)'	System	05 Sep 2020 00:10:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-04T20:10:20', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '8a6c77a2-4f11-4a25-98a7-8955d340ad02'	System	05 Sep 2020 00:10:24
User entered '04 Sep 2020 20:10'	System	05 Sep 2020 00:10:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 6'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-05T19:34:36', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'fb6d5bdd-43e0-4e12-ac91-322a51dc80dc'	System	05 Sep 2020 23:34:52
User entered 'None (0)'	System	05 Sep 2020 23:34:52

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-05T19:34:38', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'fb6d5bdd-43e0-4e12-ac91-322a51dc80dc'	System	05 Sep 2020 23:34:52
User entered 'None (0)'	System	05 Sep 2020 23:34:52

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-05T19:34:40', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'fb6d5bdd-43e0-4e12-ac91-322a51dc80dc'	System	05 Sep 2020 23:34:52
User entered 'None (0)'	System	05 Sep 2020 23:34:52

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-05T19:34:41', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'fb6d5bdd-43e0-4e12-ac91-322a51dc80dc'	System	05 Sep 2020 23:34:52
User entered 'None (0)'	System	05 Sep 2020 23:34:52

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-05T19:34:43', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'fb6d5bdd-43e0-4e12-ac91-322a51dc80dc'	System	05 Sep 2020 23:34:52
User entered 'None (0)'	System	05 Sep 2020 23:34:52

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-05T19:34:44', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'fb6d5bdd-43e0-4e12-ac91-322a51dc80dc'	System	05 Sep 2020 23:34:52
User entered 'None (0)'	System	05 Sep 2020 23:34:52

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-05T19:34:47', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'fb6d5bdd-43e0-4e12-ac91-322a51dc80dc'	System	05 Sep 2020 23:34:52
User entered 'No (N)'	System	05 Sep 2020 23:34:52

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-05T19:34:50', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'fb6d5bdd-43e0-4e12-ac91-322a51dc80dc'	System	05 Sep 2020 23:34:52
User entered '05 Sep 2020 19:34'	System	05 Sep 2020 23:34:52

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 7'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-06T20:05:49', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '847077ed-c5d8-470c-9b99-086a90bf9684'	System	07 Sep 2020 00:06:09
User entered 'None (0)'	System	07 Sep 2020 00:06:09

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-06T20:05:50', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '847077ed-c5d8-470c-9b99-086a90bf9684'	System	07 Sep 2020 00:06:09
User entered 'None (0)'	System	07 Sep 2020 00:06:09

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-06T20:05:52', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '847077ed-c5d8-470c-9b99-086a90bf9684'	System	07 Sep 2020 00:06:09
User entered 'None (0)'	System	07 Sep 2020 00:06:09

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-06T20:05:54', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '847077ed-c5d8-470c-9b99-086a90bf9684'	System	07 Sep 2020 00:06:09
User entered 'None (0)'	System	07 Sep 2020 00:06:09

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-06T20:05:56', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '847077ed-c5d8-470c-9b99-086a90bf9684'	System	07 Sep 2020 00:06:09
User entered 'None (0)'	System	07 Sep 2020 00:06:09

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-06T20:05:57', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '847077ed-c5d8-470c-9b99-086a90bf9684'	System	07 Sep 2020 00:06:09
User entered 'None (0)'	System	07 Sep 2020 00:06:09

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-06T20:06:01', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '847077ed-c5d8-470c-9b99-086a90bf9684'	System	07 Sep 2020 00:06:09
User entered 'No (N)'	System	07 Sep 2020 00:06:09

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-06T20:06:04', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '847077ed-c5d8-470c-9b99-086a90bf9684'	System	07 Sep 2020 00:06:09
User entered '06 Sep 2020 20:06'	System	07 Sep 2020 00:06:09

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:59:24

US3412337

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:08:50

US3412337

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '08 Sep 2020'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:08:50

US3412337

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Contact Made (CONTACT MADE)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:08:50

US3412337

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:08:50

US3412337

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:08:57

US3412337

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'I'	System	10 Sep 2020 17:08:57

US3412337

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Mason Urban (b) (4)	14 Sep 2020 13:49:59

US3412337

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '14 Sep 2020'	Mason Urban (b) (4)	14 Sep 2020 13:49:59

US3412337

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	14 Sep 2020 13:49:59

US3412337

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Mason Urban (b) (4)	14 Sep 2020 13:49:59

US3412337

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Mason Urban (b) (4)	14 Sep 2020 13:50:04

US3412337

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'I'	System	14 Sep 2020 13:50:04

US3412337

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Mason Urban (b) (4)	21 Sep 2020 18:58:02

US3412337

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '21 Sep 2020'	Mason Urban (b) (4)	21 Sep 2020 18:58:02

US3412337

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	21 Sep 2020 18:58:02

US3412337

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Mason Urban (b) (4)	21 Sep 2020 18:58:02

US3412337

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Mason Urban (b) (4)	21 Sep 2020 18:58:13

US3412337

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'I'	System	21 Sep 2020 18:58:13

US3412337

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Steven Anderson (b) (4)	28 Sep 2020 15:48:56

US3412337

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '28 Sep 2020'	Steven Anderson (b) (4)	28 Sep 2020 15:48:56

US3412337

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Home (Home)'	Steven Anderson (b) (4)	28 Sep 2020 15:48:56

US3412337

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'VISIT2'	System	28 Sep 2020 15:48:56

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User accepted default value 'Pre-Dose (PREDOSE)'	Steven Anderson (b) (4)	28 Sep 2020 15:49:48
	(b) (4)	

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Steven Anderson (b) (4)	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '28 Sep 2020'	Steven Anderson (b) (4)	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '10:44'	Steven Anderson (b) (4)	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered '28 Sep 2020 10:44'	System	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '36.7' C	Steven Anderson (b) (4)	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Oral (Oral)'	Steven Anderson (b) (4)	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Steven Anderson (b) (4)	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '68'	Steven Anderson (b) (4)	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'bpm'	System	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '13'	Steven Anderson (b) (4)	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'breaths/min'	System	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '136'	Steven Anderson (b) (4)	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'mmHg'	System	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '70'	Steven Anderson (b) (4)	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'mmHg'	System	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User accepted default value 'Post-Dose (POSTDOSE)'	Steven Anderson (b) (4)	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	29 Sep 2020 17:53:15
User entered 'No (N)'	Steven Anderson (b) (4)	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '28 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	29 Sep 2020 17:53:15
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	28 Sep 2020 15:49:48
	(b) (4)	

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '12:06' reason for change: Data Entry Error	Melissa Fuson (b) (4)	29 Sep 2020 17:53:15
User entered empty.	Steven Anderson (b) (4)	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered '28 Sep 2020 12:06'	System	29 Sep 2020 17:53:15
User entered empty.	System	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '98.1' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	29 Sep 2020 17:53:15
User entered empty.	Steven Anderson (b) (4)	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Oral (Oral)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	29 Sep 2020 17:53:15
User entered empty.	Steven Anderson (b) (4)	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Steven Anderson (b) (4)	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '62' reason for change: Data Entry Error	Melissa Fuson (b) (4)	29 Sep 2020 17:53:15
User entered empty.	Steven Anderson (b) (4)	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'bpm'	System	29 Sep 2020 17:53:15
User entered empty.	System	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '16' reason for change: Data Entry Error	Melissa Fuson (b) (4)	29 Sep 2020 17:53:15
User entered empty.	Steven Anderson (b) (4)	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'breaths/min'	System	29 Sep 2020 17:53:15
User entered empty.	System	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '128' reason for change: Data Entry Error	Melissa Fuson (b) (4)	29 Sep 2020 17:53:15
User entered empty.	Steven Anderson (b) (4)	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'mmHg'	System	29 Sep 2020 17:53:15
User entered empty.	System	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '70' reason for change: Data Entry Error	Melissa Fuson (b) (4)	29 Sep 2020 17:53:15
User entered empty.	Steven Anderson (b) (4)	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'mmHg'	System	29 Sep 2020 17:53:15
User entered empty.	System	28 Sep 2020 15:49:48

US3412337

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Steven Anderson (b) (4)	28 Sep 2020 15:49:58

US3412337

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '28 Sep 2020'	Steven Anderson (b) (4)	28 Sep 2020 15:49:58

US3412337

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Steven Anderson (b) (4)	28 Sep 2020 15:50:24

US3412337

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Steven Anderson (b) (4)	28 Sep 2020 15:50:24

US3412337

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:32

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)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Steven Anderson (b) (4)	28 Sep 2020 15:50:24

US3412337

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:32

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'MRNA-1273 OR PLACEBO'	System	28 Sep 2020 15:50:24

US3412337

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '28 Sep 2020'	Steven Anderson (b) (4)	28 Sep 2020 15:50:24

US3412337

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '11:30'	Steven Anderson (b) (4)	28 Sep 2020 15:50:24

US3412337

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered '28 Sep 2020 11:30'	System	28 Sep 2020 15:50:24

US3412337

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Left Arm (LEFT ARM)'	Steven Anderson (b) (4)	28 Sep 2020 15:50:24

US3412337

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'ONCE'	System	28 Sep 2020 15:50:24

US3412337

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'INTRAMUSCULAR'	System	28 Sep 2020 15:50:24

US3412337

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Steven Anderson (b) (4)	28 Sep 2020 15:50:45

US3412337

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '28 Sep 2020'	Steven Anderson (b) (4)	28 Sep 2020 15:50:45

US3412337

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '10:59'	Steven Anderson (b) (4)	28 Sep 2020 15:50:45

US3412337

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered '28 Sep 2020 10:59'	System	28 Sep 2020 15:50:45

US3412337

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:31:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '28 Sep 2020'	Steven Anderson (b) (4)	28 Sep 2020 15:51:04

US3412337

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Steven Anderson (b) (4)	28 Sep 2020 15:51:04

US3412337

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Steven Anderson (b) (4)	28 Sep 2020 15:51:04

US3412337

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '11:03'	Steven Anderson (b) (4)	28 Sep 2020 15:51:04

US3412337

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered '28 Sep 2020 11:03'	System	28 Sep 2020 15:51:04

US3412337

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Steven Anderson (b) (4)	28 Sep 2020 15:51:04

US3412337

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'No (N)'	Steven Anderson (b) (4)	28 Sep 2020 15:51:04

US3412337

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Steven Anderson (b) (4)	28 Sep 2020 15:51:04

US3412337

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered empty.	System	28 Sep 2020 15:51:04

US3412337

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Steven Anderson (b) (4)	28 Sep 2020 15:51:22

US3412337

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'I'	System	28 Sep 2020 15:51:22

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T12:12:36', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '00c5e8f5-5989-47d0-a75d-55793a60f6de'	System	28 Sep 2020 16:12:59
User entered 'Yes (Y)'	System	28 Sep 2020 16:12:59

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T12:12:45', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '00c5e8f5-5989-47d0-a75d-55793a60f6de' User entered '98.1'	System	28 Sep 2020 16:12:59

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T12:12:49', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '00c5e8f5-5989-47d0-a75d-55793a60f6de'	System	28 Sep 2020 16:12:59
User entered 'No (N)'	System	28 Sep 2020 16:12:59

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T12:12:55', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '00c5e8f5-5989-47d0-a75d-55793a60f6de'	System	28 Sep 2020 16:12:59
User entered '28 Sep 2020 12:12'	System	28 Sep 2020 16:12:59

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '28 Sep 2020 11:50'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '28 Sep 2020 14:20'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T20:01:12', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '1d2880ec-c940-427c-b4cf-820ddffbb911'	System	29 Sep 2020 00:01:41
User entered 'Yes (Y)'	System	29 Sep 2020 00:01:41

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T20:01:23', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '1d2880ec-c940-427c-b4cf-820ddffbb911'	System	29 Sep 2020 00:01:41
User entered '99.6'	System	29 Sep 2020 00:01:41

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T20:01:27', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '1d2880ec-c940-427c-b4cf-820ddffbb911'	System	29 Sep 2020 00:01:41
User entered 'No (N)'	System	29 Sep 2020 00:01:41

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T20:01:31', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '1d2880ec-c940-427c-b4cf-820ddffbb911'	System	29 Sep 2020 00:01:41
User entered '28 Sep 2020 20:01'	System	29 Sep 2020 00:01:41

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '28 Sep 2020 15:15'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 2'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-29T19:30:45', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '430c5c57-f48d-480e-ae2b-ea2d34676e75'	System	29 Sep 2020 23:31:10
User entered 'Yes (Y)'	System	29 Sep 2020 23:31:10

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-29T19:30:50', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '430c5c57-f48d-480e-ae2b-ea2d34676e75'	System	29 Sep 2020 23:31:10
User entered '96.9'	System	29 Sep 2020 23:31:10

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-29T19:30:54', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '430c5c57-f48d-480e-ae2b-ea2d34676e75'	System	29 Sep 2020 23:31:10
User entered 'Yes (Y)'	System	29 Sep 2020 23:31:10

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
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 'patient was contacted. ' (Site from System).	(b) (4)	23 Oct 2020 05:36:46
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).	Jacob sekinger (b) (4)	09 Oct 2020 17:05:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-29T19:30:59', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '430c5c57-f48d-480e-ae2b-ea2d34676e75'	(b) (4)	
User entered '1'	System	29 Sep 2020 23:31:10

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:32

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-29T19:30:59', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '430c5c57-f48d-480e-ae2b-ea2d34676e75'	System	29 Sep 2020 23:31:10
User entered '0'	System	29 Sep 2020 23:31:10

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-29T19:31:04', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '430c5c57-f48d-480e-ae2b-ea2d34676e75'	System	29 Sep 2020 23:31:10
User entered '29 Sep 2020 19:31'	System	29 Sep 2020 23:31:10

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 3'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-30T19:31:59', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'bc282c8a-feb8-4567-9c56-ef70c87c124d'	System	30 Sep 2020 23:32:21
User entered 'Yes (Y)'	System	30 Sep 2020 23:32:21

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-30T19:32:05', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'bc282c8a-feb8-4567-9c56-ef70c87c124d'	System	30 Sep 2020 23:32:21
User entered '97.4'	System	30 Sep 2020 23:32:21

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-30T19:32:13', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'bc282c8a-feb8-4567-9c56-ef70c87c124d'	System	30 Sep 2020 23:32:21
User entered 'No (N)'	System	30 Sep 2020 23:32:21

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-30T19:32:17', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'bc282c8a-feb8-4567-9c56-ef70c87c124d'	System	30 Sep 2020 23:32:21
User entered '30 Sep 2020 19:32'	System	30 Sep 2020 23:32:21

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 4'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-01T19:35:38', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '67577058-e117-48cd-bc13-3307ea3aab3c'	System	01 Oct 2020 23:35:53
User entered 'Yes (Y)'	System	01 Oct 2020 23:35:53

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-01T19:35:42', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '67577058-e117-48cd-bc13-3307ea3aab3c'	System	01 Oct 2020 23:35:53
User entered '97.8'	System	01 Oct 2020 23:35:53

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-01T19:35:46', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '67577058-e117-48cd-bc13-3307ea3aab3c'	System	01 Oct 2020 23:35:53
User entered 'No (N)'	System	01 Oct 2020 23:35:53

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-01T19:35:49', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '67577058-e117-48cd-bc13-3307ea3aab3c'	System	01 Oct 2020 23:35:53
User entered '01 Oct 2020 19:35'	System	01 Oct 2020 23:35:53

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 5'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-02T19:21:11', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'c1e5a936-ed90-4fd1-8a85-cead5efa1477'	System	02 Oct 2020 23:21:30
User entered 'Yes (Y)'	System	02 Oct 2020 23:21:30

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-02T19:21:20', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'c1e5a936-ed90-4fd1-8a85-cead5efa1477'	System	02 Oct 2020 23:21:30
User entered '96.7'	System	02 Oct 2020 23:21:30

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-02T19:21:23', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'c1e5a936-ed90-4fd1-8a85-cead5efa1477'	System	02 Oct 2020 23:21:30
User entered 'No (N)'	System	02 Oct 2020 23:21:30

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-02T19:21:27', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'c1e5a936-ed90-4fd1-8a85-cead5efa1477'	System	02 Oct 2020 23:21:30
User entered '02 Oct 2020 19:21'	System	02 Oct 2020 23:21:30

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 6'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-03T19:27:17', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '1b82bc6e-c0c2-456f-9837-41647bf88e1e'	System	03 Oct 2020 23:28:09
User entered 'Yes (Y)'	System	03 Oct 2020 23:28:09

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-03T19:27:28', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '1b82bc6e-c0c2-456f-9837-41647bf88e1e'	System	03 Oct 2020 23:28:09
User entered '98.0'	System	03 Oct 2020 23:28:09

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-03T19:28:03', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '1b82bc6e-c0c2-456f-9837-41647bf88e1e'	System	03 Oct 2020 23:28:09
User entered 'No (N)'	System	03 Oct 2020 23:28:09

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-03T19:28:07', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '1b82bc6e-c0c2-456f-9837-41647bf88e1e'	System	03 Oct 2020 23:28:09
User entered '03 Oct 2020 19:28'	System	03 Oct 2020 23:28:09

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 7'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-04T20:09:47', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '20d36cd5-e30e-4831-b275-a0b9bde0dc12'	System	05 Oct 2020 00:10:00
User entered 'Yes (Y)'	System	05 Oct 2020 00:10:00

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-04T20:09:52', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '20d36cd5-e30e-4831-b275-a0b9bde0dc12'	System	05 Oct 2020 00:10:00
User entered '97.8'	System	05 Oct 2020 00:10:00

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-04T20:09:55', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '20d36cd5-e30e-4831-b275-a0b9bde0dc12'	System	05 Oct 2020 00:10:00
User entered 'No (N)'	System	05 Oct 2020 00:10:00

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-04T20:09:58', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '20d36cd5-e30e-4831-b275-a0b9bde0dc12'	System	05 Oct 2020 00:10:00
User entered '04 Oct 2020 20:09'	System	05 Oct 2020 00:10:00

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T12:13:03', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'be1902e9-720e-4e53-ae4-b32a52346683'	System	28 Sep 2020 16:13:24
User entered 'None (1)'	System	28 Sep 2020 16:13:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T12:13:07', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'be1902e9-720e-4e53-ae4-b32a52346683'	System	28 Sep 2020 16:13:24
User entered 'No (N)'	System	28 Sep 2020 16:13:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T12:13:10', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'be1902e9-720e-4e53-ae4-b32a52346683'	System	28 Sep 2020 16:13:24
User entered 'No (N)'	System	28 Sep 2020 16:13:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T12:13:14', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'be1902e9-720e-4e53-ae4-b32a52346683'	System	28 Sep 2020 16:13:24
User entered 'None (1)'	System	28 Sep 2020 16:13:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T12:13:18', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'be1902e9-720e-4e53-ae4-b32a52346683'	System	28 Sep 2020 16:13:24
User entered '28 Sep 2020 12:13'	System	28 Sep 2020 16:13:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '28 Sep 2020 11:50'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '28 Sep 2020 14:20'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T20:01:46', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f21518fd-cf9d-4e36-857a-c9d9d1a2f36e'	System	29 Sep 2020 00:02:12
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 00:02:12

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T20:01:54', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f21518fd-cf9d-4e36-857a-c9d9d1a2f36e'	System	29 Sep 2020 00:02:12
User entered 'No (N)'	System	29 Sep 2020 00:02:12

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T20:02:03', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f21518fd-cf9d-4e36-857a-c9d9d1a2f36e'	System	29 Sep 2020 00:02:12
User entered 'No (N)'	System	29 Sep 2020 00:02:12

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T20:02:07', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f21518fd-cf9d-4e36-857a-c9d9d1a2f36e'	System	29 Sep 2020 00:02:12
User entered 'None (1)'	System	29 Sep 2020 00:02:12

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T20:02:10', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f21518fd-cf9d-4e36-857a-c9d9d1a2f36e'	System	29 Sep 2020 00:02:12
User entered '28 Sep 2020 20:02'	System	29 Sep 2020 00:02:12

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '28 Sep 2020 15:15'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 2'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-29T19:31:27', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'b57b269d-3113-48d4-839c-9ab920ee2ced'	System	29 Sep 2020 23:31:47
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 23:31:47

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-29T19:31:30', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'b57b269d-3113-48d4-839c-9ab920ee2ced'	System	29 Sep 2020 23:31:47
User entered 'No (N)'	System	29 Sep 2020 23:31:47

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-29T19:31:34', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'b57b269d-3113-48d4-839c-9ab920ee2ced'	System	29 Sep 2020 23:31:47
User entered 'No (N)'	System	29 Sep 2020 23:31:47

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-29T19:31:37', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'b57b269d-3113-48d4-839c-9ab920ee2ced'	System	29 Sep 2020 23:31:47
User entered 'None (1)'	System	29 Sep 2020 23:31:47

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-29T19:31:41', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'b57b269d-3113-48d4-839c-9ab920ee2ced'	System	29 Sep 2020 23:31:47
User entered '29 Sep 2020 19:31'	System	29 Sep 2020 23:31:47

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 3'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-30T19:32:24', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '3e24d91b-1de9-4836-b774-13830e1134f9'	System	30 Sep 2020 23:32:49
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 23:32:49

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-30T19:32:31', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '3e24d91b-1de9-4836-b774-13830e1134f9'	System	30 Sep 2020 23:32:49
User entered 'No (N)'	System	30 Sep 2020 23:32:49

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-30T19:32:35', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '3e24d91b-1de9-4836-b774-13830e1134f9'	System	30 Sep 2020 23:32:49
User entered 'No (N)'	System	30 Sep 2020 23:32:49

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-30T19:32:38', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '3e24d91b-1de9-4836-b774-13830e1134f9'	System	30 Sep 2020 23:32:49
User entered 'None (1)'	System	30 Sep 2020 23:32:49

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-30T19:32:43', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '3e24d91b-1de9-4836-b774-13830e1134f9'	System	30 Sep 2020 23:32:49
User entered '30 Sep 2020 19:32'	System	30 Sep 2020 23:32:49

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 4'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-01T19:35:55', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '5738a482-957f-4c6f-9822-b765c662f6ed'	System	01 Oct 2020 23:36:10
User entered 'Does not interfere with activity (2)'	System	01 Oct 2020 23:36:10

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-01T19:35:58', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '5738a482-957f-4c6f-9822-b765c662f6ed'	System	01 Oct 2020 23:36:10
User entered 'No (N)'	System	01 Oct 2020 23:36:10

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-01T19:36:00', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '5738a482-957f-4c6f-9822-b765c662f6ed'	System	01 Oct 2020 23:36:10
User entered 'No (N)'	System	01 Oct 2020 23:36:10

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-01T19:36:02', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '5738a482-957f-4c6f-9822-b765c662f6ed'	System	01 Oct 2020 23:36:10
User entered 'None (1)'	System	01 Oct 2020 23:36:10

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-01T19:36:05', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '5738a482-957f-4c6f-9822-b765c662f6ed'	System	01 Oct 2020 23:36:10
User entered '01 Oct 2020 19:36'	System	01 Oct 2020 23:36:10

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 5'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-02T19:21:34', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '736d423f-a89a-4e9a-9e4b-884cfa2e1c54'	System	02 Oct 2020 23:21:48
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 23:21:48

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-02T19:21:38', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '736d423f-a89a-4e9a-9e4b-884cfa2e1c54'	System	02 Oct 2020 23:21:48
User entered 'No (N)'	System	02 Oct 2020 23:21:48

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-02T19:21:40', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '736d423f-a89a-4e9a-9e4b-884cfa2e1c54'	System	02 Oct 2020 23:21:48
User entered 'No (N)'	System	02 Oct 2020 23:21:48

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-02T19:21:43', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '736d423f-a89a-4e9a-9e4b-884cfa2e1c54'	System	02 Oct 2020 23:21:48
User entered 'None (1)'	System	02 Oct 2020 23:21:48

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-02T19:21:46', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '736d423f-a89a-4e9a-9e4b-884cfa2e1c54'	System	02 Oct 2020 23:21:48
User entered '02 Oct 2020 19:21'	System	02 Oct 2020 23:21:48

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 6'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-03T19:28:12', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '2f74ce7a-9537-4fb3-b1e5-e32429903f51'	System	03 Oct 2020 23:28:25
User entered 'None (1)'	System	03 Oct 2020 23:28:25

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-03T19:28:15', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '2f74ce7a-9537-4fb3-b1e5-e32429903f51'	System	03 Oct 2020 23:28:25
User entered 'No (N)'	System	03 Oct 2020 23:28:25

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-03T19:28:17', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '2f74ce7a-9537-4fb3-b1e5-e32429903f51'	System	03 Oct 2020 23:28:25
User entered 'No (N)'	System	03 Oct 2020 23:28:25

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-03T19:28:20', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '2f74ce7a-9537-4fb3-b1e5-e32429903f51'	System	03 Oct 2020 23:28:25
User entered 'None (1)'	System	03 Oct 2020 23:28:25

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-03T19:28:23', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '2f74ce7a-9537-4fb3-b1e5-e32429903f51'	System	03 Oct 2020 23:28:25
User entered '03 Oct 2020 19:28'	System	03 Oct 2020 23:28:25

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 7'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-04T20:10:04', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'e85e460b-4ab8-4da8-8c59-5491f7774750'	System	05 Oct 2020 00:10:15
User entered 'None (1)'	System	05 Oct 2020 00:10:15

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-04T20:10:06', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'e85e460b-4ab8-4da8-8c59-5491f7774750'	System	05 Oct 2020 00:10:15
User entered 'No (N)'	System	05 Oct 2020 00:10:15

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-04T20:10:08', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'e85e460b-4ab8-4da8-8c59-5491f7774750'	System	05 Oct 2020 00:10:15
User entered 'No (N)'	System	05 Oct 2020 00:10:15

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-04T20:10:10', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'e85e460b-4ab8-4da8-8c59-5491f7774750'	System	05 Oct 2020 00:10:15
User entered 'None (1)'	System	05 Oct 2020 00:10:15

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-04T20:10:13', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'e85e460b-4ab8-4da8-8c59-5491f7774750'	System	05 Oct 2020 00:10:15
User entered '04 Oct 2020 20:10'	System	05 Oct 2020 00:10:15

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T12:13:25', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'b63f9b39-23c4-41ff-9bd2-b7d265ff5858'	System	28 Sep 2020 16:13:51
User entered 'None (0)'	System	28 Sep 2020 16:13:51

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T12:13:28', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'b63f9b39-23c4-41ff-9bd2-b7d265ff5858'	System	28 Sep 2020 16:13:51
User entered 'None (0)'	System	28 Sep 2020 16:13:51

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T12:13:31', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'b63f9b39-23c4-41ff-9bd2-b7d265ff5858'	System	28 Sep 2020 16:13:51
User entered 'None (0)'	System	28 Sep 2020 16:13:51

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T12:13:34', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'b63f9b39-23c4-41ff-9bd2-b7d265ff5858'	System	28 Sep 2020 16:13:51
User entered 'None (0)'	System	28 Sep 2020 16:13:51

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T12:13:36', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'b63f9b39-23c4-41ff-9bd2-b7d265ff5858'	System	28 Sep 2020 16:13:51
User entered 'None (0)'	System	28 Sep 2020 16:13:51

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T12:13:39', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'b63f9b39-23c4-41ff-9bd2-b7d265ff5858'	System	28 Sep 2020 16:13:51
User entered 'None (0)'	System	28 Sep 2020 16:13:51

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T12:13:42', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'b63f9b39-23c4-41ff-9bd2-b7d265ff5858'	System	28 Sep 2020 16:13:51
User entered 'No (N)'	System	28 Sep 2020 16:13:51

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T12:13:45', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'b63f9b39-23c4-41ff-9bd2-b7d265ff5858'	System	28 Sep 2020 16:13:51
User entered '28 Sep 2020 12:13'	System	28 Sep 2020 16:13:51

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '28 Sep 2020 11:50'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '28 Sep 2020 14:20'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T20:02:15', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '16ff15b4-b5ac-4a51-a075-f752f639967b'	System	29 Sep 2020 00:02:39
User entered 'None (0)'	System	29 Sep 2020 00:02:39

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T20:02:18', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '16ff15b4-b5ac-4a51-a075-f752f639967b'	System	29 Sep 2020 00:02:39
User entered 'None (0)'	System	29 Sep 2020 00:02:39

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T20:02:21', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '16ff15b4-b5ac-4a51-a075-f752f639967b'	System	29 Sep 2020 00:02:39
User entered 'None (0)'	System	29 Sep 2020 00:02:39

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T20:02:24', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '16ff15b4-b5ac-4a51-a075-f752f639967b'	System	29 Sep 2020 00:02:39
User entered 'None (0)'	System	29 Sep 2020 00:02:39

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T20:02:28', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '16ff15b4-b5ac-4a51-a075-f752f639967b'	System	29 Sep 2020 00:02:39
User entered 'None (0)'	System	29 Sep 2020 00:02:39

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T20:02:30', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '16ff15b4-b5ac-4a51-a075-f752f639967b'	System	29 Sep 2020 00:02:39
User entered 'None (0)'	System	29 Sep 2020 00:02:39

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T20:02:35', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '16ff15b4-b5ac-4a51-a075-f752f639967b'	System	29 Sep 2020 00:02:39
User entered 'No (N)'	System	29 Sep 2020 00:02:39

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-28T20:02:38', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '16ff15b4-b5ac-4a51-a075-f752f639967b'	System	29 Sep 2020 00:02:39
User entered '28 Sep 2020 20:02'	System	29 Sep 2020 00:02:39

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '28 Sep 2020 15:15'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 2'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-29T19:31:48', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '3e522230-8043-4ff8-a0da-588c1536f42f'	System	29 Sep 2020 23:32:25
User entered 'No interference with activity (1)'	System	29 Sep 2020 23:32:25

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-29T19:31:57', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '3e522230-8043-4ff8-a0da-588c1536f42f'	System	29 Sep 2020 23:32:25
User entered 'No interference with activity (1)'	System	29 Sep 2020 23:32:25

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-29T19:32:02', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '3e522230-8043-4ff8-a0da-588c1536f42f'	System	29 Sep 2020 23:32:25
User entered 'Some interference with activity (2)'	System	29 Sep 2020 23:32:25

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-29T19:32:06', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '3e522230-8043-4ff8-a0da-588c1536f42f'	System	29 Sep 2020 23:32:25
User entered 'Some interference with activity (2)'	System	29 Sep 2020 23:32:25

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-29T19:32:10', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '3e522230-8043-4ff8-a0da-588c1536f42f'	System	29 Sep 2020 23:32:25
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	29 Sep 2020 23:32:25

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-29T19:32:13', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '3e522230-8043-4ff8-a0da-588c1536f42f'	System	29 Sep 2020 23:32:25
User entered 'None (0)'	System	29 Sep 2020 23:32:25

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-29T19:32:17', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '3e522230-8043-4ff8-a0da-588c1536f42f' User entered 'No (N)'	System	29 Sep 2020 23:32:25
	System	29 Sep 2020 23:32:25

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-29T19:32:20', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '3e522230-8043-4ff8-a0da-588c1536f42f'	System	29 Sep 2020 23:32:25
User entered '29 Sep 2020 19:32'	System	29 Sep 2020 23:32:25

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 3'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-30T19:32:53', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '86d95d44-8442-4ca5-acd7-5dd59b781a57'	System	30 Sep 2020 23:33:27
User entered 'None (0)'	System	30 Sep 2020 23:33:27

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-30T19:33:02', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '86d95d44-8442-4ca5-acd7-5dd59b781a57'	System	30 Sep 2020 23:33:27
User entered 'None (0)'	System	30 Sep 2020 23:33:27

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-30T19:33:05', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '86d95d44-8442-4ca5-acd7-5dd59b781a57'	System	30 Sep 2020 23:33:27
User entered 'None (0)'	System	30 Sep 2020 23:33:27

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-30T19:33:07', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '86d95d44-8442-4ca5-acd7-5dd59b781a57'	System	30 Sep 2020 23:33:27
User entered 'None (0)'	System	30 Sep 2020 23:33:27

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-30T19:33:09', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '86d95d44-8442-4ca5-acd7-5dd59b781a57'	System	30 Sep 2020 23:33:27
User entered 'None (0)'	System	30 Sep 2020 23:33:27

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-30T19:33:13', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '86d95d44-8442-4ca5-acd7-5dd59b781a57'	System	30 Sep 2020 23:33:27
User entered 'None (0)'	System	30 Sep 2020 23:33:27

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-30T19:33:18', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '86d95d44-8442-4ca5-acd7-5dd59b781a57'	System	30 Sep 2020 23:33:27
User entered 'No (N)'	System	30 Sep 2020 23:33:27

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-09-30T19:33:21', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '86d95d44-8442-4ca5-acd7-5dd59b781a57'	System	30 Sep 2020 23:33:27
User entered '30 Sep 2020 19:33'	System	30 Sep 2020 23:33:27

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 4'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-01T19:36:11', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'bcdce554-259c-44ce-8708-250ab9cf2905'	System	01 Oct 2020 23:36:33
User entered 'None (0)'	System	01 Oct 2020 23:36:33

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-01T19:36:12', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'bcdce554-259c-44ce-8708-250ab9cf2905'	System	01 Oct 2020 23:36:33
User entered 'None (0)'	System	01 Oct 2020 23:36:33

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-01T19:36:14', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'bcdce554-259c-44ce-8708-250ab9cf2905'	System	01 Oct 2020 23:36:33
User entered 'None (0)'	System	01 Oct 2020 23:36:33

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-01T19:36:16', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'bcdce554-259c-44ce-8708-250ab9cf2905'	System	01 Oct 2020 23:36:33
User entered 'None (0)'	System	01 Oct 2020 23:36:33

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-01T19:36:18', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'bcdce554-259c-44ce-8708-250ab9cf2905'	System	01 Oct 2020 23:36:33
User entered 'None (0)'	System	01 Oct 2020 23:36:33

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-01T19:36:20', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'bcdce554-259c-44ce-8708-250ab9cf2905'	System	01 Oct 2020 23:36:33
User entered 'None (0)'	System	01 Oct 2020 23:36:33

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-01T19:36:23', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'bcdce554-259c-44ce-8708-250ab9cf2905'	System	01 Oct 2020 23:36:33
User entered 'No (N)'	System	01 Oct 2020 23:36:33

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-01T19:36:26', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'bcdce554-259c-44ce-8708-250ab9cf2905'	System	01 Oct 2020 23:36:33
User entered '01 Oct 2020 19:36'	System	01 Oct 2020 23:36:33

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 5'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-02T19:21:49', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '0de61836-2b17-44ef-b8b8-07e1e0ce1fd6'	System	02 Oct 2020 23:22:27
User entered 'None (0)'	System	02 Oct 2020 23:22:27

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-02T19:21:51', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '0de61836-2b17-44ef-b8b8-07e1e0ce1fd6'	System	02 Oct 2020 23:22:27
User entered 'None (0)'	System	02 Oct 2020 23:22:27

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-02T19:21:53', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '0de61836-2b17-44ef-b8b8-07e1e0ce1fd6'	System	02 Oct 2020 23:22:27
User entered 'None (0)'	System	02 Oct 2020 23:22:27

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-02T19:21:54', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '0de61836-2b17-44ef-b8b8-07e1e0ce1fd6'	System	02 Oct 2020 23:22:27
User entered 'None (0)'	System	02 Oct 2020 23:22:27

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-02T19:21:56', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '0de61836-2b17-44ef-b8b8-07e1e0ce1fd6'	System	02 Oct 2020 23:22:27
User entered 'None (0)'	System	02 Oct 2020 23:22:27

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-02T19:21:57', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '0de61836-2b17-44ef-b8b8-07e1e0ce1fd6'	System	02 Oct 2020 23:22:27
User entered 'None (0)'	System	02 Oct 2020 23:22:27

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-02T19:22:00', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '0de61836-2b17-44ef-b8b8-07e1e0ce1fd6'	System	02 Oct 2020 23:22:27
User entered 'No (N)'	System	02 Oct 2020 23:22:27

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-02T19:22:24', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '0de61836-2b17-44ef-b8b8-07e1e0ce1fd6'	System	02 Oct 2020 23:22:27
User entered '02 Oct 2020 19:22'	System	02 Oct 2020 23:22:27

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 6'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-03T19:28:29', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '92f201d9-e842-49e6-bbb9-cc5074958bcd'	System	03 Oct 2020 23:28:51
User entered 'None (0)'	System	03 Oct 2020 23:28:51

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-03T19:28:32', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '92f201d9-e842-49e6-bbb9-cc5074958bcd'	System	03 Oct 2020 23:28:51
User entered 'None (0)'	System	03 Oct 2020 23:28:51

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-03T19:28:33', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '92f201d9-e842-49e6-bbb9-cc5074958bcd'	System	03 Oct 2020 23:28:51
User entered 'None (0)'	System	03 Oct 2020 23:28:51

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-03T19:28:36', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '92f201d9-e842-49e6-bbb9-cc5074958bcd'	System	03 Oct 2020 23:28:51
User entered 'None (0)'	System	03 Oct 2020 23:28:51

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-03T19:28:39', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '92f201d9-e842-49e6-bbb9-cc5074958bcd'	System	03 Oct 2020 23:28:51
User entered 'None (0)'	System	03 Oct 2020 23:28:51

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-03T19:28:43', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '92f201d9-e842-49e6-bbb9-cc5074958bcd'	System	03 Oct 2020 23:28:51
User entered 'None (0)'	System	03 Oct 2020 23:28:51

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-03T19:28:45', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '92f201d9-e842-49e6-bbb9-cc5074958bcd'	System	03 Oct 2020 23:28:51
User entered 'No (N)'	System	03 Oct 2020 23:28:51

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-03T19:28:48', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '92f201d9-e842-49e6-bbb9-cc5074958bcd'	System	03 Oct 2020 23:28:51
User entered '03 Oct 2020 19:28'	System	03 Oct 2020 23:28:51

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	28 Sep 2020 15:50:24
User entered 'Day 7'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-04T20:10:18', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'e0f2bdf0-9a05-4c11-b504-0fec43ab055f'	System	05 Oct 2020 00:10:37
User entered 'None (0)'	System	05 Oct 2020 00:10:37

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-04T20:10:20', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'e0f2bdf0-9a05-4c11-b504-0fec43ab055f'	System	05 Oct 2020 00:10:37
User entered 'None (0)'	System	05 Oct 2020 00:10:37

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-04T20:10:22', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'e0f2bdf0-9a05-4c11-b504-0fec43ab055f' User entered 'None (0)'	System	05 Oct 2020 00:10:37
	System	05 Oct 2020 00:10:37

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-04T20:10:24', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'e0f2bdf0-9a05-4c11-b504-0fec43ab055f' User entered 'None (0)'	System	05 Oct 2020 00:10:37
	System	05 Oct 2020 00:10:37

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-04T20:10:25', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'e0f2bdf0-9a05-4c11-b504-0fec43ab055f' User entered 'None (0)'	System	05 Oct 2020 00:10:37
	System	05 Oct 2020 00:10:37

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-04T20:10:27', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'e0f2bdf0-9a05-4c11-b504-0fec43ab055f'	System	05 Oct 2020 00:10:37
User entered 'None (0)'	System	05 Oct 2020 00:10:37

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-04T20:10:31', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'e0f2bdf0-9a05-4c11-b504-0fec43ab055f'	System	05 Oct 2020 00:10:37
User entered 'No (N)'	System	05 Oct 2020 00:10:37

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-10-04T20:10:34', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'e0f2bdf0-9a05-4c11-b504-0fec43ab055f'	System	05 Oct 2020 00:10:37
User entered '04 Oct 2020 20:10'	System	05 Oct 2020 00:10:37

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 15:50:24

US3412337

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 15:50:24

US3412337

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:26:45

US3412337

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:26:45

US3412337

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:26:45

US3412337

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:26:45

US3412337

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:26:50

US3412337

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'I'	System	05 Oct 2020 14:26:50

US3412337

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Mason Urban (b) (4)	12 Oct 2020 15:40:54

US3412337

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '12 Oct 2020'	Mason Urban (b) (4)	12 Oct 2020 15:40:54

US3412337

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	12 Oct 2020 15:40:54

US3412337

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Mason Urban (b) (4)	12 Oct 2020 15:40:54

US3412337

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Mason Urban (b) (4)	12 Oct 2020 15:40:59

US3412337

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'I'	System	12 Oct 2020 15:40:59

US3412337

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Mason Urban (b) (4)	19 Oct 2020 14:01:40

US3412337

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '19 Oct 2020'	Mason Urban (b) (4)	19 Oct 2020 14:01:40

US3412337

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	19 Oct 2020 14:01:40

US3412337

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Mason Urban (b) (4)	19 Oct 2020 14:01:40

US3412337

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Mason Urban (b) (4)	19 Oct 2020 14:01:26

US3412337

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'I'	System	19 Oct 2020 14:01:26

US3412337

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	26 Oct 2020 14:39:58

US3412337

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '26 Oct 2020'	Melissa Fuson (b) (4)	26 Oct 2020 14:39:58

US3412337

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4)	26 Oct 2020 14:39:58

US3412337

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'VISIT3'	System	26 Oct 2020 14:39:58

US3412337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'No (N)'	Melissa Fuson (b) (4)	26 Oct 2020 14:40:12

US3412337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 14:40:12

US3412337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 14:40:12

US3412337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered empty.	System	26 Oct 2020 14:40:12

US3412337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 14:40:12

US3412337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 14:40:12

US3412337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 14:40:12

US3412337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 14:40:12

US3412337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered empty.	System	26 Oct 2020 14:40:12

US3412337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 14:40:12

US3412337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered empty.	System	26 Oct 2020 14:40:12

US3412337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 14:40:12

US3412337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered empty.	System	26 Oct 2020 14:40:12

US3412337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 14:40:12

US3412337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered empty.	System	26 Oct 2020 14:40:12

US3412337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39

US3412337

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39

US3412337

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'No (N)'	Melissa Fuson (b) (4)	26 Oct 2020 14:40:23

US3412337

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 14:40:23

US3412337

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	26 Oct 2020 14:40:44

US3412337

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User closed query 'Per GCL Lab Reconciliation: Per GCL, no immunogenicity sample was received for the Visit 3 Day 57 on 26OCT2020. Please clarify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 10:16:25
Query 'Per GCL Lab Reconciliation: Per GCL, no immunogenicity sample was received for the Visit 3 Day 57 on 26OCT2020. Please clarify and update as appropriate. ' answered with 'confirmed with source, sample was collected on 26Oct2020' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	02 Nov 2020 15:56:10
User opened query 'Per GCL Lab Reconciliation: Per GCL, no immunogenicity sample was received for the Visit 3 Day 57 on 26OCT2020. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 00:31:43
User entered '26 Oct 2020'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 14:40:44

US3412337

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered '10:15'	Melissa Fuson (b) (4)	26 Oct 2020 14:40:44

US3412337

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered '26 Oct 2020 10:15'	System	26 Oct 2020 14:40:44

US3412337

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:40:59
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	26 Oct 2020 14:40:53

US3412337

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'I'	System	26 Oct 2020 14:40:53

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 64'	System	31 Aug 2020 15:59:24

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Have you been exposed to someone with 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 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Please 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 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Please 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 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Please 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 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37

US3412337

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37
Data entry locked.	System	31 Aug 2020 15:59:24
User entered '31 Oct 2020 00:01'	System	31 Aug 2020 15:59:24

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:39:49
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 20:52:37
Data entry locked.	System	31 Aug 2020 15:59:24
User entered '04 Nov 2020 23:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 71'	System	31 Aug 2020 15:59:24

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-11-07T07:06:38', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '2322038d-05d2-4614-abcb-1534b0b02f13'	System	07 Nov 2020 12:07:12
User entered 'No (N)'	System	07 Nov 2020 12:07:12

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Have you been exposed to someone with 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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-11-07T07:07:01', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '2322038d-05d2-4614-abcb-1534b0b02f13'	System	07 Nov 2020 12:07:12
User entered 'No (N)'	System	07 Nov 2020 12:07:12

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-11-07T07:07:07', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '2322038d-05d2-4614-abcb-1534b0b02f13'	System	07 Nov 2020 12:07:12
User entered '07 Nov 2020 07:07:07'	System	07 Nov 2020 12:07:12

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered '07 Nov 2020 00:01'	System	31 Aug 2020 15:59:24

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered '11 Nov 2020 23:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered 'Day 78'	System	31 Aug 2020 15:59:24

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-11-15T08:59:07', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'a13db098-4cbd-4c5f-9f8c-4a295c5f2a93'	System	15 Nov 2020 13:59:28
User entered 'No (N)'	System	15 Nov 2020 13:59:28

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Have you been exposed to someone with 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 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-11-15T08:59:20', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'a13db098-4cbd-4c5f-9f8c-4a295c5f2a93'	System	15 Nov 2020 13:59:28
User entered 'No (N)'	System	15 Nov 2020 13:59:28

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-11-15T08:59:25', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'a13db098-4cbd-4c5f-9f8c-4a295c5f2a93'	System	15 Nov 2020 13:59:28
User entered '15 Nov 2020 08:59:25'	System	15 Nov 2020 13:59:28

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered '14 Nov 2020 00:01'	System	31 Aug 2020 15:59:24

US3412337

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:32:51
Data entry locked.	System	31 Aug 2020 15:59:24
User entered '18 Nov 2020 23:59'	System	31 Aug 2020 15:59:24

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (f8d7b9300a9d9227)', Time: '2020-11-21T09:13:46', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '438ee1ec-1d88-4e22-9eb9-745c1b05a325'	System	21 Nov 2020 14:14:01
User entered 'No (N)'	System	21 Nov 2020 14:14:01

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Have you been exposed to someone with 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 (f8d7b9300a9d9227)', Time: '2020-11-21T09:13:51', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '438ee1ec-1d88-4e22-9eb9-745c1b05a325'	System	21 Nov 2020 14:14:01
User entered 'No (N)'	System	21 Nov 2020 14:14:01

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-11-21T09:13:56', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '438ee1ec-1d88-4e22-9eb9-745c1b05a325'	System	21 Nov 2020 14:14:01
User entered '21 Nov 2020 09:13:56'	System	21 Nov 2020 14:14:01

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (f8d7b9300a9d9227)', Time: '2020-11-25T06:51:25', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '780762c1-09b6-4f65-9149-75680c1deca5'	System	25 Nov 2020 11:51:35
User entered 'No (N)'	System	25 Nov 2020 11:51:35

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Have you been exposed to someone with 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 (f8d7b9300a9d9227)', Time: '2020-11-25T06:51:30', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '780762c1-09b6-4f65-9149-75680c1deca5'	System	25 Nov 2020 11:51:35
User entered 'No (N)'	System	25 Nov 2020 11:51:35

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-11-25T06:51:33', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '780762c1-09b6-4f65-9149-75680c1deca5' User entered '25 Nov 2020 06:51:33'	System	25 Nov 2020 11:51:35

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (f8d7b9300a9d9227)', Time: '2020-12-02T08:10:18', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'b0a7525f-ad97-4887-8f1e-b695c1eb51f6'	System	02 Dec 2020 13:10:34
User entered 'No (N)'	System	02 Dec 2020 13:10:34

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Have you been exposed to someone with 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 (f8d7b9300a9d9227)', Time: '2020-12-02T08:10:24', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'b0a7525f-ad97-4887-8f1e-b695c1eb51f6'	System	02 Dec 2020 13:10:34
User entered 'No (N)'	System	02 Dec 2020 13:10:34

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-12-02T08:10:28', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'b0a7525f-ad97-4887-8f1e-b695c1eb51f6'	System	02 Dec 2020 13:10:34
User entered '02 Dec 2020 08:10:28'	System	02 Dec 2020 13:10:34

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (f8d7b9300a9d9227)', Time: '2020-12-09T08:55:33', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '8a345458-9b5f-4caf-b842-c2d785f58dd9'	System	09 Dec 2020 13:55:48
User entered 'No (N)'	System	09 Dec 2020 13:55:48

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Have you been exposed to someone with 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 (f8d7b9300a9d9227)', Time: '2020-12-09T08:55:39', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '8a345458-9b5f-4caf-b842-c2d785f58dd9'	System	09 Dec 2020 13:55:48
User entered 'No (N)'	System	09 Dec 2020 13:55:48

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-12-09T08:55:43', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '8a345458-9b5f-4caf-b842-c2d785f58dd9'	System	09 Dec 2020 13:55:48
User entered '09 Dec 2020 08:55:43'	System	09 Dec 2020 13:55:48

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (f8d7b9300a9d9227)', Time: '2020-12-16T09:22:41', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '9c115d80-1173-4949-9a0c-cb305ee73fb3'	System	16 Dec 2020 14:22:52
User entered 'No (N)'	System	16 Dec 2020 14:22:52

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Have you been exposed to someone with 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 (f8d7b9300a9d9227)', Time: '2020-12-16T09:22:44', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '9c115d80-1173-4949-9a0c-cb305ee73fb3'	System	16 Dec 2020 14:22:52
User entered 'No (N)'	System	16 Dec 2020 14:22:52

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-12-16T09:22:48', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '9c115d80-1173-4949-9a0c-cb305ee73fb3' User entered '16 Dec 2020 09:22:48'	System	16 Dec 2020 14:22:52
	System	16 Dec 2020 14:22:52

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (f8d7b9300a9d9227)', Time: '2020-12-23T08:31:06', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '5a143679-1f1f-4c53-aec0-aaf0d8599d25'	System	23 Dec 2020 13:31:16
User entered 'No (N)'	System	23 Dec 2020 13:31:16

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Have you been exposed to someone with 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 (f8d7b9300a9d9227)', Time: '2020-12-23T08:31:09', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '5a143679-1f1f-4c53-aec0-aaf0d8599d25'	System	23 Dec 2020 13:31:16
User entered 'No (N)'	System	23 Dec 2020 13:31:16

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2020-12-23T08:31:12', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '5a143679-1f1f-4c53-aec0-aaf0d8599d25'	System	23 Dec 2020 13:31:16
User entered '23 Dec 2020 08:31:12'	System	23 Dec 2020 13:31:16

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (f8d7b9300a9d9227)', Time: '2021-01-01T19:38:20', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'da7f04ee-453d-4632-bf08-47e9edf12414'	System	02 Jan 2021 00:38:33
User entered 'No (N)'	System	02 Jan 2021 00:38:33

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Have you been exposed to someone with 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 (f8d7b9300a9d9227)', Time: '2021-01-01T19:38:27', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'da7f04ee-453d-4632-bf08-47e9edf12414'	System	02 Jan 2021 00:38:33
User entered 'No (N)'	System	02 Jan 2021 00:38:33

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2021-01-01T19:38:30', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'da7f04ee-453d-4632-bf08-47e9edf12414'	System	02 Jan 2021 00:38:33
User entered '01 Jan 2021 19:38:30'	System	02 Jan 2021 00:38:33

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (f8d7b9300a9d9227)', Time: '2021-01-06T02:48:29', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '36cf2df0-746b-48b7-9fd7-7a7d64cc068a'	System	06 Jan 2021 07:48:43
User entered 'No (N)'	System	06 Jan 2021 07:48:43

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Have you been exposed to someone with 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 (f8d7b9300a9d9227)', Time: '2021-01-06T02:48:33', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '36cf2df0-746b-48b7-9fd7-7a7d64cc068a'	System	06 Jan 2021 07:48:43
User entered 'No (N)'	System	06 Jan 2021 07:48:43

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2021-01-06T02:48:37', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '36cf2df0-746b-48b7-9fd7-7a7d64cc068a' User entered '06 Jan 2021 02:48:37'	System	06 Jan 2021 07:48:43

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (f8d7b9300a9d9227)', Time: '2021-01-13T07:12:15', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '3c932570-bd72-4a89-82c2-5f9bfa0147bd'	System	13 Jan 2021 12:12:28
User entered 'No (N)'	System	13 Jan 2021 12:12:28

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Have you been exposed to someone with 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 (f8d7b9300a9d9227)', Time: '2021-01-13T07:12:17', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '3c932570-bd72-4a89-82c2-5f9bfa0147bd'	System	13 Jan 2021 12:12:28
User entered 'No (N)'	System	13 Jan 2021 12:12:28

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2021-01-13T07:12:23', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '3c932570-bd72-4a89-82c2-5f9bfa0147bd' User entered '13 Jan 2021 07:12:23'	System	13 Jan 2021 12:12:28
	System	13 Jan 2021 12:12:28

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (f8d7b9300a9d9227)', Time: '2021-01-20T06:45:48', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'd8f14704-d028-4d73-a7cd-a0f109281dcc'	System	20 Jan 2021 11:46:03
User entered 'No (N)'	System	20 Jan 2021 11:46:03

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Have you been exposed to someone with 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 (f8d7b9300a9d9227)', Time: '2021-01-20T06:45:56', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'd8f14704-d028-4d73-a7cd-a0f109281dcc'	System	20 Jan 2021 11:46:03
User entered 'No (N)'	System	20 Jan 2021 11:46:03

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2021-01-20T06:46:00', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'd8f14704-d028-4d73-a7cd-a0f109281dcc' User entered '20 Jan 2021 06:46:00'	System	20 Jan 2021 11:46:03

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (f8d7b9300a9d9227)', Time: '2021-01-29T12:01:19', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '4a00487e-2929-43b5-a740-d75f980336df'	System	29 Jan 2021 17:04:12
User entered 'No (N)'	System	29 Jan 2021 17:04:12

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Have you been exposed to someone with 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 (f8d7b9300a9d9227)', Time: '2021-01-29T12:01:24', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '4a00487e-2929-43b5-a740-d75f980336df'	System	29 Jan 2021 17:04:12
User entered 'No (N)'	System	29 Jan 2021 17:04:12

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2021-01-29T12:01:28', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '4a00487e-2929-43b5-a740-d75f980336df' User entered '29 Jan 2021 12:01:28'	System	29 Jan 2021 17:04:12

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (f8d7b9300a9d9227)', Time: '2021-02-03T10:04:27', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'ef8d6046-7211-41d8-8160-1cbb025b267d'	System	03 Feb 2021 15:04:37
User entered 'No (N)'	System	03 Feb 2021 15:04:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Have you been exposed to someone with 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 (f8d7b9300a9d9227)', Time: '2021-02-03T10:04:30', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'ef8d6046-7211-41d8-8160-1cbb025b267d'	System	03 Feb 2021 15:04:37
User entered 'No (N)'	System	03 Feb 2021 15:04:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f8d7b9300a9d9227)', Time: '2021-02-03T10:04:33', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'ef8d6046-7211-41d8-8160-1cbb025b267d'	System	03 Feb 2021 15:04:37
User entered '03 Feb 2021 10:04:33'	System	03 Feb 2021 15:04:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (d91a16f655cbe975)', Time: '2021-02-12T11:49:34', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'ee1cc511-0351-4665-8e8f-9d3dad4ec306'	System	12 Feb 2021 16:49:42
User entered 'No (N)'	System	12 Feb 2021 16:49:42

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Have you been exposed to someone with 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 (d91a16f655cbe975)', Time: '2021-02-12T11:49:38', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'ee1cc511-0351-4665-8e8f-9d3dad4ec306'	System	12 Feb 2021 16:49:42
User entered 'No (N)'	System	12 Feb 2021 16:49:42

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d91a16f655cbe975)', Time: '2021-02-12T11:49:41', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'ee1cc511-0351-4665-8e8f-9d3dad4ec306'	System	12 Feb 2021 16:49:42
User entered '12 Feb 2021 11:49:41'	System	12 Feb 2021 16:49:42

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (d91a16f655cbe975)', Time: '2021-02-17T07:30:04', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '1d150291-e68f-4512-b5fe-2418ae450129'	System	17 Feb 2021 12:30:17
User entered 'No (N)'	System	17 Feb 2021 12:30:17

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Have you been exposed to someone with 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 (d91a16f655cbe975)', Time: '2021-02-17T07:30:09', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '1d150291-e68f-4512-b5fe-2418ae450129'	System	17 Feb 2021 12:30:17
User entered 'No (N)'	System	17 Feb 2021 12:30:17

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d91a16f655cbe975)', Time: '2021-02-17T07:30:14', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '1d150291-e68f-4512-b5fe-2418ae450129'	System	17 Feb 2021 12:30:17
User entered '17 Feb 2021 07:30:14'	System	17 Feb 2021 12:30:17

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (d91a16f655cbe975)', Time: '2021-02-24T08:08:33', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f6fa7645-8063-4a07-b0ba-b656f6dfb863'	System	24 Feb 2021 13:09:19
User entered 'Yes (Y)'	System	24 Feb 2021 13:09:19

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Have you been exposed to someone with 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 (d91a16f655cbe975)', Time: '2021-02-24T08:08:37', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f6fa7645-8063-4a07-b0ba-b656f6dfb863'	System	24 Feb 2021 13:09:19
User entered 'No (N)'	System	24 Feb 2021 13:09:19

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (d91a16f655cbe975)', Time: '2021-02-24T08:08:42', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f6fa7645-8063-4a07-b0ba-b656f6dfb863'	System	24 Feb 2021 13:09:19
User entered 'No (N)'	System	24 Feb 2021 13:09:19

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (d91a16f655cbe975)', Time: '2021-02-24T08:08:47', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f6fa7645-8063-4a07-b0ba-b656f6dfb863'	System	24 Feb 2021 13:09:19
User entered 'Yes (Y)'	System	24 Feb 2021 13:09:19

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Please 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 (d91a16f655cbe975)', Time: '2021-02-24T08:09:01', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f6fa7645-8063-4a07-b0ba-b656f6dfb863'	System	24 Feb 2021 13:09:19
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Feb 2021 13:09:19

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d91a16f655cbe975)', Time: '2021-02-24T08:09:06', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'f6fa7645-8063-4a07-b0ba-b656f6dfb863' User entered '24 Feb 2021 08:09:06'	System	24 Feb 2021 13:09:19
	System	24 Feb 2021 13:09:19

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (d91a16f655cbe975)', Time: '2021-03-03T06:23:47', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '273f1ee3-1d00-40e7-9c71-3bd4af5682a4'	System	03 Mar 2021 11:23:55
User entered 'No (N)'	System	03 Mar 2021 11:23:55

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Have you been exposed to someone with 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 (d91a16f655cbe975)', Time: '2021-03-03T06:23:53', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '273f1ee3-1d00-40e7-9c71-3bd4af5682a4'	System	03 Mar 2021 11:23:55
User entered 'No (N)'	System	03 Mar 2021 11:23:55

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d91a16f655cbe975)', Time: '2021-03-03T06:23:57', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '273f1ee3-1d00-40e7-9c71-3bd4af5682a4' User entered '03 Mar 2021 06:23:57'	System	03 Mar 2021 11:23:55
	System	03 Mar 2021 11:23:55

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (d91a16f655cbe975)', Time: '2021-03-10T09:03:44', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '95dccd1e-8660-4188-84f5-948da10e3146'	System	10 Mar 2021 14:03:56
User entered 'No (N)'	System	10 Mar 2021 14:03:56

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Have you been exposed to someone with 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 (d91a16f655cbe975)', Time: '2021-03-10T09:03:51', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '95dccd1e-8660-4188-84f5-948da10e3146'	System	10 Mar 2021 14:03:56
User entered 'No (N)'	System	10 Mar 2021 14:03:56

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d91a16f655cbe975)', Time: '2021-03-10T09:03:55', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '95dccd1e-8660-4188-84f5-948da10e3146'	System	10 Mar 2021 14:03:56
User entered '10 Mar 2021 09:03:55'	System	10 Mar 2021 14:03:56

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (d91a16f655cbe975)', Time: '2021-03-17T07:42:22', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'cb9ef2e2-b174-45ea-a7ba-69375e4fee18'	System	17 Mar 2021 11:42:28
User entered 'No (N)'	System	17 Mar 2021 11:42:28

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Have you been exposed to someone with 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 (d91a16f655cbe975)', Time: '2021-03-17T07:42:25', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'cb9ef2e2-b174-45ea-a7ba-69375e4fee18'	System	17 Mar 2021 11:42:28
User entered 'No (N)'	System	17 Mar 2021 11:42:28

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d91a16f655cbe975)', Time: '2021-03-17T07:42:29', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'cb9ef2e2-b174-45ea-a7ba-69375e4fee18'	System	17 Mar 2021 11:42:28
User entered '17 Mar 2021 07:42:29'	System	17 Mar 2021 11:42:28

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (d91a16f655cbe975)', Time: '2021-03-24T08:42:01', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '464773b0-3b8d-426d-9086-f5ef15bde20d'	System	24 Mar 2021 12:42:11
User entered 'No (N)'	System	24 Mar 2021 12:42:11

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Have you been exposed to someone with 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 (d91a16f655cbe975)', Time: '2021-03-24T08:42:05', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '464773b0-3b8d-426d-9086-f5ef15bde20d'	System	24 Mar 2021 12:42:11
User entered 'No (N)'	System	24 Mar 2021 12:42:11

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d91a16f655cbe975)', Time: '2021-03-24T08:42:08', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '464773b0-3b8d-426d-9086-f5ef15bde20d'	System	24 Mar 2021 12:42:11
User entered '24 Mar 2021 08:42:08'	System	24 Mar 2021 12:42:11

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (d91a16f655cbe975)', Time: '2021-04-02T15:50:06', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'ccbab22d-a625-4e06-861c-aea8d27f9038'	System	02 Apr 2021 19:50:16
User entered 'No (N)'	System	02 Apr 2021 19:50:16

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Have you been exposed to someone with 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 (d91a16f655cbe975)', Time: '2021-04-02T15:50:09', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'ccbab22d-a625-4e06-861c-aea8d27f9038'	System	02 Apr 2021 19:50:16
User entered 'No (N)'	System	02 Apr 2021 19:50:16

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d91a16f655cbe975)', Time: '2021-04-02T15:50:12', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: 'ccbab22d-a625-4e06-861c-aea8d27f9038'	System	02 Apr 2021 19:50:16
User entered '02 Apr 2021 15:50:12'	System	02 Apr 2021 19:50:16

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (d91a16f655cbe975)', Time: '2021-04-07T10:17:53', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '6489c74a-cdc7-4832-b9b3-a0d9699236ef'	System	07 Apr 2021 14:18:05
User entered 'No (N)'	System	07 Apr 2021 14:18:05

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Have you been exposed to someone with 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 (d91a16f655cbe975)', Time: '2021-04-07T10:17:55', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '6489c74a-cdc7-4832-b9b3-a0d9699236ef'	System	07 Apr 2021 14:18:05
User entered 'No (N)'	System	07 Apr 2021 14:18:05

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d91a16f655cbe975)', Time: '2021-04-07T10:18:01', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '6489c74a-cdc7-4832-b9b3-a0d9699236ef' User entered '07 Apr 2021 10:18:01'	System	07 Apr 2021 14:18:05
	System	07 Apr 2021 14:18:05

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (d91a16f655cbe975)', Time: '2021-04-14T07:34:03', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '0fad5d27-7c8a-45e6-906f-16092af78c5f'	System	14 Apr 2021 11:34:12
User entered 'No (N)'	System	14 Apr 2021 11:34:12

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Have you been exposed to someone with 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 (d91a16f655cbe975)', Time: '2021-04-14T07:34:06', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '0fad5d27-7c8a-45e6-906f-16092af78c5f'	System	14 Apr 2021 11:34:12
User entered 'No (N)'	System	14 Apr 2021 11:34:12

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d91a16f655cbe975)', Time: '2021-04-14T07:34:11', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '0fad5d27-7c8a-45e6-906f-16092af78c5f' User entered '14 Apr 2021 07:34:11'	System	14 Apr 2021 11:34:12

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[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 (d91a16f655cbe975)', Time: '2021-04-21T07:39:26', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '72a650d4-f9bd-4eab-bc5f-7cf9e5019c67'	System	21 Apr 2021 11:39:37
User entered 'No (N)'	System	21 Apr 2021 11:39:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

Have you been exposed to someone with 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 (d91a16f655cbe975)', Time: '2021-04-21T07:39:29', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '72a650d4-f9bd-4eab-bc5f-7cf9e5019c67'	System	21 Apr 2021 11:39:37
User entered 'No (N)'	System	21 Apr 2021 11:39:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d91a16f655cbe975)', Time: '2021-04-21T07:39:33', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '72a650d4-f9bd-4eab-bc5f-7cf9e5019c67'	System	21 Apr 2021 11:39:37
User entered '21 Apr 2021 07:39:33'	System	21 Apr 2021 11:39:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '26 Oct 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '30 Oct 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '02 Nov 2022 00:01'	System	19 Nov 2020 20:52:37

US3412337

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:52:37
Amendment Manager: User entered '06 Nov 2022 23:59'	System	19 Nov 2020 20:52:37

US3412337

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:31:32

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 08:39:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d91a16f655cbe975)', Time: '2021-03-02T10:20:18', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '34cb183b-dbf3-4be7-a8b0-14b28af35ced'	System	02 Mar 2021 15:20:23
User entered 'No (N)'	System	02 Mar 2021 15:20:23

US3412337

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:31:32

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:39:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d91a16f655cbe975)', Time: '2021-03-02T10:20:23', User OID: 'PatientReportedOutcome (US3412337)', ODM File OID: '34cb183b-dbf3-4be7-a8b0-14b28af35ced'	System	02 Mar 2021 15:20:23
User entered '02 Mar 2021 10:20:23'	System	02 Mar 2021 15:20:23

US3412337

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:43:07
User entered 'Yes (Y)'	Mason Urban (b) (4)	28 Dec 2020 17:06:01

US3412337

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:43:07
User entered '23 Nov 2020'	Mason Urban (b) (4)	28 Dec 2020 17:06:01

US3412337

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:43:07
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	28 Dec 2020 17:06:01

US3412337

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:43:07
User entered empty.	Mason Urban (b) (4)	28 Dec 2020 17:06:01

US3412337

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:43:07
User entered 'Yes (Y)'	Mason Urban (b) (4)	28 Dec 2020 17:06:05

US3412337

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:26:39
User entered 'I'	System	28 Dec 2020 17:06:05

US3412337

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:46:17
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered 'Yes (Y)'	Mason Urban (b) (4)	28 Dec 2020 17:06:15

US3412337

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:46:17
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered '28 Dec 2020'	Mason Urban (b) (4)	28 Dec 2020 17:06:15

US3412337

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:46:17
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	28 Dec 2020 17:06:15

US3412337

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:46:17
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered empty.	Mason Urban (b) (4)	28 Dec 2020 17:06:15

US3412337

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:46:17
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered 'Yes (Y)'	Mason Urban (b) (4)	28 Dec 2020 17:06:22

US3412337

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:46:17
User entered 'I'	System	28 Dec 2020 17:06:22

US3412337

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:46:17
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered 'Yes (Y)'	Mason Urban (b) (4)	26 Jan 2021 16:21:17

US3412337

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:46:17
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered '26 Jan 2021'	Mason Urban (b) (4)	26 Jan 2021 16:21:17

US3412337

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:46:17
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	26 Jan 2021 16:21:17

US3412337

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:46:17
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered empty.	Mason Urban (b) (4)	26 Jan 2021 16:21:17

US3412337

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:46:17
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered 'Yes (Y)'	Mason Urban (b) (4)	26 Jan 2021 16:21:21

US3412337

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:46:17
User entered 'I'	System	26 Jan 2021 16:21:21

US3412337

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:46:17
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	29 Mar 2021 20:42:25

US3412337

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:46:17
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered '25 Feb 2021'	Andrea Newlands (b) (4)	29 Mar 2021 20:42:25

US3412337

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:46:17
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered 'Contact Made (CONTACT MADE)'	Andrea Newlands (b) (4)	29 Mar 2021 20:42:25

US3412337

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:46:17
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	29 Mar 2021 20:42:25
	(b) (4)	

US3412337

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:46:17
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	29 Mar 2021 20:44:50

US3412337

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:46:17
User entered 'I'	System	29 Mar 2021 20:44:50

US3412337

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	29 Mar 2021 20:47:34
	(b) (4)	

US3412337

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
	(b) (4)	
User entered '29 Mar 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4)	29 Mar 2021 20:48:33
	(b) (4)	
User entered '24 Mar 2021'	Andrea Newlands (b) (4)	29 Mar 2021 20:47:34
	(b) (4)	

US3412337

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
	(b) (4)	
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4)	29 Mar 2021 20:47:34
	(b) (4)	

US3412337

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	29 Mar 2021 20:47:34

US3412337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 20:47:40
	(b) (4)	

US3412337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 20:47:40
	(b) (4)	

US3412337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 20:47:40
	(b) (4)	

US3412337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 20:47:40

US3412337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 20:47:40
	(b) (4)	

US3412337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 20:47:40
	(b) (4)	

US3412337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 20:47:40
	(b) (4)	

US3412337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 20:47:40
	(b) (4)	

US3412337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 20:47:40

US3412337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 20:47:40
	(b) (4)	

US3412337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 20:47:40

US3412337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 20:47:40
	(b) (4)	

US3412337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 20:47:40

US3412337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 20:47:40
	(b) (4)	

US3412337

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 20:47:40

US3412337

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 20:47:53
	(b) (4)	

US3412337

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 20:47:53
	(b) (4)	

US3412337

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	29 Mar 2021 20:48:12
	(b) (4)	

US3412337

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
	(b) (4)	
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Mar 2021 20:48:33
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		29 Mar 2021 20:48:33
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Mar 2021 20:48:28
User entered '29 Mar 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4)	29 Mar 2021 20:48:28
	(b) (4)	
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Mar 2021 20:48:22
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		29 Mar 2021 20:48:22
User entered '24 Mar 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4)	29 Mar 2021 20:48:22
	(b) (4)	
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Mar 2021 20:48:12
User entered '29 Mar 2021'	Andrea Newlands (b) (4)	29 Mar 2021 20:48:12
	(b) (4)	

US3412337

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
	(b) (4)	
User entered '11:10'	Andrea Newlands (b) (4)	29 Mar 2021 20:48:12
	(b) (4)	

US3412337

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
User entered '29 Mar 2021 11:10'	System	29 Mar 2021 20:48:28
User entered '24 Mar 2021 11:10'	System	29 Mar 2021 20:48:22
User entered '29 Mar 2021 11:10'	System	29 Mar 2021 20:48:12

US3412337

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	29 Mar 2021 20:48:39
	(b) (4)	

US3412337

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:32

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 20:48:39

US3412337

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

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	05 Jan 2021 15:59:10

US3412337

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

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered '5 Jan 2021'	Melissa Fuson (b) (4)	05 Jan 2021 15:59:10

US3412337

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

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4)	05 Jan 2021 15:59:10

US3412337

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

Form: Visit Date

Generated On: 09 Jun 2021 17:31:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered 'UNBLND_DECIDE'	System	05 Jan 2021 15:59:10

US3412337

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

Form: Unblinding

Generated On: 09 Jun 2021 17:31:32

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered '5 Jan 2021'	Melissa Fuson (b) (4)	05 Jan 2021 15:59:38

US3412337

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

Form: Unblinding

Generated On: 09 Jun 2021 17:31:32

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered '0'	Andrea Newlands (b) (4)	24 Mar 2021 19:46:49
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:21:29

US3412337

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

Form: Unblinding

Generated On: 09 Jun 2021 17:31:32

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	05 Jan 2021 15:59:38

US3412337

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

Form: Unblinding

Generated On: 09 Jun 2021 17:31:32

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User closed query 'please complete' (Site from CRA).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:12:23
User entered 'Amendment 6 or later (Amendment 6 or later)'	Andrea Newlands (b) (4)	24 Mar 2021 19:46:49
Query 'please complete' answered with 'updated' (Site from CRA).	(b) (4) Andrea Newlands (b) (4)	24 Mar 2021 19:46:46
User opened query 'please complete' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 18:34:22
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:21:29

US3412337

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

Form: Unblinding

Generated On: 09 Jun 2021 17:31:32

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered '5 Jan 2021'	Melissa Fuson (b) (4)	05 Jan 2021 15:59:38

US3412337

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

Form: Unblinding

Generated On: 09 Jun 2021 17:31:32

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered 'mRNA-1273 (mRNA-1273)'	Melissa Fuson (b) (4)	05 Jan 2021 15:59:38

US3412337

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

Form: Unblinding

Generated On: 09 Jun 2021 17:31:32

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 13:27:40
User entered 'mRNA-1273 (mRNA-1273)'	Melissa Fuson (b) (4)	05 Jan 2021 15:59:38
	(b) (4)	

US3412337

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

Form: Unblinding

Generated On: 09 Jun 2021 17:31:32

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 13:27:40
User entered 'mRNA-1273 (mRNA-1273)'	Melissa Fuson (b) (4)	05 Jan 2021 15:59:38
	(b) (4)	

US3412337

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

Form: Unblinding

Generated On: 09 Jun 2021 17:31:32

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered 'No (N)'	Melissa Fuson (b) (4)	05 Jan 2021 15:59:38

US3412337

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

Form: Unblinding

Generated On: 09 Jun 2021 17:31:32

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered empty.	System	05 Jan 2021 15:59:38

US3412337

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

Form: Unblinding

Generated On: 09 Jun 2021 17:31:32

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered empty.	System	05 Jan 2021 15:59:38

US3412337

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	05 Jan 2021 16:01:45

US3412337

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered '5 Jan 2021'	Melissa Fuson (b) (4)	05 Jan 2021 16:01:45

US3412337

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered '20:25'	Melissa Fuson (b) (4)	05 Jan 2021 16:01:45

US3412337

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered '5 Jan 2021 20:25'	System	05 Jan 2021 16:01:45

US3412337

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:31:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	05 Jan 2021 16:02:03

US3412337

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:31:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered '5 Jan 2021'	Melissa Fuson (b) (4)	05 Jan 2021 16:02:03

US3412337

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered '10:28'	Melissa Fuson (b) (4)	05 Jan 2021 16:02:03

US3412337

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:58:13
User entered '5 Jan 2021 10:28'	System	05 Jan 2021 16:02:03

US3412337

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:31:32

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:50
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:42:43
User entered 'Yes (Y)'	Steven Anderson (b) (4)	24 Feb 2021 20:16:19

US3412337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:46:01
User entered 'USA-US061-2021-mRNA-1273-P301000010'	System	25 Feb 2021 17:24:56
User entered 'New'	(b) (4), (b) (6)	25 Feb 2021 17:24:56

US3412337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 16:46:03
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hip fracture, LLT: Hip fracture - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 20:21:00
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 20:21:00
	(b) (4)	
Data point term sent to Coder	System	24 Feb 2021 20:20:18
User entered 'Left hip fracture'	Steven Anderson (b) (4)	24 Feb 2021 20:19:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:46:05
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	24 Feb 2021 20:19:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:46:07
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	24 Feb 2021 20:19:45

US3412337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:46:09
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	24 Feb 2021 20:19:45

US3412337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:37:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '22 Feb 2021'	Steven Anderson (b) (4)	24 Feb 2021 20:19:45
	(b) (4)	

US3412337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:37:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	24 Feb 2021 20:19:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 20:19:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:37:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	14 Apr 2021 20:13:22
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	14 Apr 2021 20:13:22
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	14 Apr 2021 20:11:26
User entered 'Yes (Y)'	Steven Anderson (b) (4)	24 Feb 2021 20:19:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:37:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:18:11
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available. ' answered with 'this sae ended when subject had surgery for her repair ' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	14 Apr 2021 20:14:14
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	14 Apr 2021 20:13:22
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	14 Apr 2021 20:13:22
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	14 Apr 2021 20:11:26
User entered '23 Feb 2021' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	14 Apr 2021 20:11:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available. ' (Site from Safety). User entered empty.	(b) (4), (b) (6) (b) (4)	05 Mar 2021 12:43:26
	Steven Anderson (b) (4) (b) (4)	24 Feb 2021 20:19:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:37:18
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	24 Feb 2021 20:19:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 20:19:45

US3412337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:37:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Steven Anderson (b) (4)	24 Feb 2021 20:19:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:37:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Yes (Y)'	Steven Anderson (b) (4)	24 Feb 2021 20:19:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:37:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '0'	Steven Anderson (b) (4)	24 Feb 2021 20:19:45
	(b) (4)	

US3412337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:37:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '0'	Steven Anderson (b) (4)	24 Feb 2021 20:19:45
	(b) (4)	

US3412337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:37:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	14 Apr 2021 19:36:08
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		14 Apr 2021 19:36:08
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	24 Feb 2021 20:19:45
User entered 'I'	Steven Anderson (b) (4)	24 Feb 2021 20:19:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:34:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '22 Feb 2021'	Steven Anderson (b) (4)	24 Feb 2021 20:19:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:34:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User closed query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 16:18:20
Query 'PV Query: Please provide the hospital discharge date when available. ' answered with 'discharge date has been provided' (Site from Safety).	Steven Anderson (b) (4)	14 Apr 2021 19:36:45
	(b) (4)	
User entered '25 Feb 2021' reason for change: Data Entry Error	Steven Anderson (b) (4)	14 Apr 2021 19:36:08
	(b) (4)	
User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 12:42:34
User entered empty.	Steven Anderson (b) (4)	24 Feb 2021 20:19:45
	(b) (4)	

US3412337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:34:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	24 Feb 2021 20:19:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:34:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	24 Feb 2021 20:19:45
	(b) (4)	

US3412337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:34:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '0'	Steven Anderson (b) (4)	24 Feb 2021 20:19:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:34:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '0'	Steven Anderson (b) (4)	24 Feb 2021 20:19:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:34:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '0'	Steven Anderson (b) (4)	24 Feb 2021 20:19:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:34:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	24 Feb 2021 20:19:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:34:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	24 Feb 2021 20:19:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:34:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Steven Anderson (b) (4)	24 Feb 2021 20:19:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:37:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '0'	Steven Anderson (b) (4)	24 Feb 2021 20:19:45
	(b) (4)	

US3412337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:38:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:18:27
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'Con meds have been updated' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	14 Apr 2021 19:38:21
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	14 Apr 2021 19:36:08
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 12:40:55
User entered '0'	Steven Anderson (b) (4) (b) (4)	24 Feb 2021 20:19:45

US3412337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:38:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 08:33:47
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'con procedures have been updated' (Site from DM).	Steven Anderson (b) (4)	14 Apr 2021 19:38:31
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 18:10:58
User entered 'I'	Steven Anderson (b) (4)	24 Feb 2021 20:19:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:38:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:18:36
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' answered with 'this sae ended when subject had surgery for her repair ' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	14 Apr 2021 20:13:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Steven Anderson (b) (4) (b) (4)	14 Apr 2021 20:13:22
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 12:40:32
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Steven Anderson (b) (4) (b) (4)	24 Feb 2021 20:19:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:38:06
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	24 Feb 2021 20:19:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
User closed query 'Records obtained. Please update narrative as appropriate' (Site from CRA).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:52:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:52:20
Query 'Records obtained. Please update narrative as appropriate' answered with 'narrative has been updated accordingly' (Site from CRA).	Steven Anderson (b) (4)	21 Apr 2021 14:30:47
Signature has been broken.	Steven Anderson (b) (4)	21 Apr 2021 14:28:58
User entered 'Subject presented to the ED as a 72 y/o female with history of COPD, Hyperlipidemia, and GERD. Subject had a fall on 22-feb-21. Received blinded mRNA-1273 on 31-aug-20 and 08-sep-20.initial presentation vital signs were sao2 95%. Physical exam significant for L hip TTP. Labs h/h 15.4/45.5. Imaging: x-ray L hip determined intertrochanter l femoral neck fracture. CXR showed large hiatal hernia and l lung base atelectasis. no new findings. left knee x-ray-wnl. Course of treatment proceeded with surgery on 23-feb-21. intramedullary nail fixation femur fracture. subject was discharged with oxycodone prn for pain, xanelto 10mg, qd, for 14 days for DVT prophylaxis, and melatonin 3mg prn for insomnia. Per subject there has been no worsening. subject progressed to PT during her hospital stay and was discharged to a rehab facility on 25-feb-2021. subject has been released and has since been seen at our site on 29-mar-21. she continues to improve and SAE is considered closed. no COVID swab documented according to medical records' reason for change: Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 14:28:58
User opened query 'Records obtained. Please update narrative as appropriate' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 13:39:00

US3412337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	19 Apr 2021 01:30:02
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'records have been faxed' (Site from Safety). User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. [mRNA-1273 protocols where subject was hospitalization during study participation]	Richard Powell (b) (4) (b) (4) (b) (4), (b) (6)	16 Apr 2021 13:33:17 15 Apr 2021 16:19:53 15 Apr 2021 16:18:44
' (Site from Safety). Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. [mRNA-1273 protocols where subject was hospitalization during study participation]	Steven Anderson (b) (4) (b) (4)	14 Apr 2021 19:41:04
' answered with 'no COVID-19 test performed per medical records' (Site from Safety).		

US3412337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[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. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 12:43:52
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. [mRNA-1273 protocols where subject was hospitalization during study participation]		05 Mar 2021 12:41:48
' (Site from Safety).		
User entered 'subject notified site on 24-feb-2021 that she fell and sustained a left hip fracture on 22-feb-2021 as a result form an accident at home in which husband stepped off ladder awkwardly, bumped into subject who fell. surgical procedure completed 23-feb-2021 for hip repair and subject remains hospitalized with likely discharge to rehab facility in the next few days. Records to be obtained'	Steven Anderson (b) (4)	24 Feb 2021 20:19:45

US3412337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Feb 2021 20:19:45

US3412337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Feb 2021 20:19:45

US3412337

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Feb 2021 20:19:45

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:50
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:46:17
User closed query 'Per CDM: DiaryDose 2, Log Line 3, ediary reports medication was taken for PAIN or FEVER, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' (Site from DM). Query 'Per CDM: DiaryDose 2, Log Line 3, ediary reports medication was taken for PAIN or FEVER, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' answered with 'VIEWED SOURCE AND WAS CONTACTED SUBJECT TOOK 500MG TYLENOL AND IT WAS ADDED TO THE MEDICATIONS LISTING' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 05:59:00
User opened query 'Per CDM: DiaryDose 2, Log Line 3, ediary reports medication was taken for PAIN or FEVER, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 14:33:29
User opened query 'Per CDM: DiaryDose 2, Log Line 3, ediary reports medication was taken for PAIN or FEVER, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 05:36:33
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:10:45

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 17:12:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:12:41
Data point term sent to Coder	System	10 Sep 2020 17:11:39
User entered 'LISINOPRIL'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:11:29

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	10 Sep 2020 17:11:29
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'HTN'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:11:29

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '5'	Mylene Asmar-Rios	10 Sep 2020 17:11:29
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	10 Sep 2020 17:11:29
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:11:29
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'once daily (QD)'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:11:29

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:11:29
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	10 Sep 2020 17:11:29
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:11:29
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'UN UNK 2005'	Mylene Asmar-Rios	10 Sep 2020 17:11:29
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	10 Sep 2020 17:11:29
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	10 Sep 2020 17:11:29
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:11:29
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:11:29

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:11:29

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:11:29

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:11:29

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
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.	(b) (4) Coder Import (b) (4)	10 Sep 2020 17:13:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:13:46
Data point term sent to Coder	System	10 Sep 2020 17:12:43
User entered 'OMEPRAZOLE'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:12:18

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	10 Sep 2020 17:12:18
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'GERD'	Mylene Asmar-Rios	10 Sep 2020 17:12:18
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '20'	Mylene Asmar-Rios	10 Sep 2020 17:12:18
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	10 Sep 2020 17:12:18
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:12:18
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'once daily (QD)'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:12:18

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:12:18
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	10 Sep 2020 17:12:18
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:12:18
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'UN UNK 1975'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:12:18

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	10 Sep 2020 17:12:18
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'Yes (Y)'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:12:18

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:12:18
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	10 Sep 2020 17:12:18
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:12:18

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:12:18

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:12:18

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 17:14:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:14:49
Data point term sent to Coder	System	10 Sep 2020 17:13:44
User entered 'PRAVASTATIN'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:13:06

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	10 Sep 2020 17:13:06
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'HYPERLIPIDEMIA'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:13:06

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '20'	Mylene Asmar-Rios	10 Sep 2020 17:13:06
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	10 Sep 2020 17:13:06
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:13:06
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'once daily (QD)'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:13:06

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:13:06
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	10 Sep 2020 17:13:06
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:13:06
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'UN UNK 2010'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:13:06

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	10 Sep 2020 17:13:06
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	10 Sep 2020 17:13:06
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:13:06
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	10 Sep 2020 17:13:06
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:13:06

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:13:06

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:13:06

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 17:16:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:16:45
Data point term sent to Coder	System	10 Sep 2020 17:15:56
User entered 'TRAZADONE'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:15:24

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	10 Sep 2020 17:15:24
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'INSOMNIA'	Mylene Asmar-Rios	10 Sep 2020 17:15:24
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '50'	Mylene Asmar-Rios	10 Sep 2020 17:15:24
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	10 Sep 2020 17:15:24
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:15:24
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'once daily (QD)'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:15:24

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:15:24
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	10 Sep 2020 17:15:24
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:15:24
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'UN UNK 2016'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:15:24

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	10 Sep 2020 17:15:24
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	10 Sep 2020 17:15:24
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:15:24
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	10 Sep 2020 17:15:24
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:15:24

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:15:24

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:15:24

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 17:17:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 17:17:48
Data point term sent to Coder	System	10 Sep 2020 17:17:01
User entered 'ALBUTEROL INHALER'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:16:39

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	10 Sep 2020 17:16:39
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'COPD'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:16:39

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '90'	Mylene Asmar-Rios	10 Sep 2020 17:16:39
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User closed query 'Per CDM: Dose unit is recorded as 'Other' and If dose unit is Other, specify is recorded as 'MCG'. However 'ug' is an available option for Dose Unit instead of Other. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:31:24
Query 'Per CDM: Dose unit is recorded as 'Other' and If dose unit is Other, specify is recorded as 'MCG'. However 'ug' is an available option for Dose Unit instead of Other. Please review and update as appropriate. ' answered with 'PER CDM CHANGED UNIT TO UG FOR MCG DOSE UNIT' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	29 Sep 2020 17:38:52
User entered 'ug (ug)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	29 Sep 2020 17:38:24
User opened query 'Per CDM: Dose unit is recorded as 'Other' and If dose unit is Other, specify is recorded as 'MCG'. However 'ug' is an available option for Dose Unit instead of Other. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 08:37:43
User entered 'Other (OTHER)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:16:39

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	29 Sep 2020 17:38:24
	(b) (4)	
User entered 'MCG'	Mylene Asmar-Rios	10 Sep 2020 17:16:39
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'as needed (PRN)'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:16:39

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:16:39
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Mylene Asmar-Rios	10 Sep 2020 17:16:39
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:16:39
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'UN UNK 2014'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:16:39

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	10 Sep 2020 17:16:39
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	10 Sep 2020 17:16:39
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:16:39
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:16:39

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:16:39

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:16:39

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:16:39

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: FORMOTEROL FUMARATE;GLYCOPYRRONIUM BROMIDE, PRODUCTSYNONYM: BEVESPI AEROSPHERE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 19:20:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 19:20:09
Data point term sent to Coder	System	10 Sep 2020 17:18:05
User entered 'BEVESPI INHALER'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:17:44

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	10 Sep 2020 17:17:44
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'COPD'	Mylene Asmar-Rios	10 Sep 2020 17:17:44
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '9/4.8'	Mylene Asmar-Rios	10 Sep 2020 17:17:44
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User closed query 'Per CDM: Dose unit is recorded as 'Other' and If dose unit is Other, specify is recorded as 'MCG'. However 'ug' is an available option for Dose Unit instead of Other. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:31:42
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	29 Sep 2020 17:39:39
Query 'Per CDM: Dose unit is recorded as 'Other' and If dose unit is Other, specify is recorded as 'MCG'. However 'ug' is an available option for Dose Unit instead of Other. Please review and update as appropriate. ' answered with 'PER CDM CHANGED UNIT TO UG FOR MCG DOSE UNIT' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	29 Sep 2020 17:39:26
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	29 Sep 2020 17:39:12
User entered 'ug (ug)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	29 Sep 2020 17:39:12
User opened query 'Per CDM: Dose unit is recorded as 'Other' and If dose unit is Other, specify is recorded as 'MCG'. However 'ug' is an available option for Dose Unit instead of Other. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 08:38:12
User entered 'Other (OTHER)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:17:44

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	29 Sep 2020 17:39:39
	(b) (4)	
User entered 'MCG'	Mylene Asmar-Rios	10 Sep 2020 17:17:44
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'once daily (QD)'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:17:44

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:17:44
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Mylene Asmar-Rios	10 Sep 2020 17:17:44
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:17:44
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'UN UNK 2014'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:17:44

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	10 Sep 2020 17:17:44
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	10 Sep 2020 17:17:44
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:17:44
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:17:44

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:17:44

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:17:44

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:17:44

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
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.	(b) (4) Coder Import (b) (4)	10 Sep 2020 17:20:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:20:44
Data point term sent to Coder	System	10 Sep 2020 17:19:06
User entered 'VITAMIN D'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:18:44

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	29 Sep 2020 17:36:40
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	10 Sep 2020 17:18:44
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'SUPPLEMENT'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:18:44

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 11:36:57
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'this is an OTC medication and the exact dosage was not provided. ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	02 Nov 2020 15:48:07
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:04:20
User entered 'I'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:18:44

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'tablet (TABLET)'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:18:44

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:18:44
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'once daily (QD)'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:18:44

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:18:44
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	10 Sep 2020 17:18:44
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:18:44
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'UN UNK 2015'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:18:44

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered '0'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:18:44

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	10 Sep 2020 17:18:44
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered empty.	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:18:44

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	10 Sep 2020 17:18:44
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:18:44

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:18:44

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:18:44

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: FIBRE, DIETARY - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Sep 2020 17:20:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:20:45
Data point term sent to Coder	System	10 Sep 2020 17:20:07
User entered 'FIBER'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:19:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	29 Sep 2020 17:36:52
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	10 Sep 2020 17:19:47
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'SUPPLEMENT'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:19:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '1'	Mylene Asmar-Rios	10 Sep 2020 17:19:47
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'tablet (TABLET)'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:19:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:19:47
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'once daily (QD)'	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:19:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:19:47
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	10 Sep 2020 17:19:47
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered empty.	(b) (4) Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:19:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'UN UNK 2015'	Mylene Asmar-Rios	10 Sep 2020 17:19:47
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	10 Sep 2020 17:19:47
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	10 Sep 2020 17:19:47
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	10 Sep 2020 17:19:47
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	10 Sep 2020 17:19:47
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:19:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:19:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:19:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
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) Coder Import (b) (4)	22 Jan 2021 14:28:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Jan 2021 14:28:04
Data point term sent to Coder	System	22 Jan 2021 14:27:09
Coding entries removed.	Jacob sekinger (b) (4)	22 Jan 2021 14:26:33
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) Coder Import (b) (4)	26 Oct 2020 15:07:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 15:07:44
Data point term sent to Coder	System	26 Oct 2020 14:38:35
User entered 'TYLENOL'	Melissa Fuson (b) (4)	26 Oct 2020 14:37:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	26 Oct 2020 14:37:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 08:35:18
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' answered with 'did not meet AE reporting criteria' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 17:08:43

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 09:04:28
User closed query 'Per CDM RQ: Response noted, however please confirm if this is Injection Site Pain and update appropriately.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 05:42:31
Query 'Per CDM RQ: Response noted, however please confirm if this is Injection Site Pain and update appropriately.' answered with 'updated. ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	22 Jan 2021 14:26:40
User entered 'SOLICITED injection site PAIN' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	22 Jan 2021 14:26:33
User opened query 'Per CDM RQ: Response noted, however please confirm if this is Injection Site Pain and update appropriately.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 18:31:23
User closed query 'Per DM CLR: Please update the indication to reflect the location of SOLICITED PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).		12 Jan 2021 18:31:23
Query 'Per DM CLR: Please update the indication to reflect the location of SOLICITED PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'medication took for solicited pain - which is noted in diary. Believe was noted as ongoing in case of pain during study. did not meet ae criteria' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	05 Jan 2021 18:41:04
User opened query 'Per DM CLR: Please update the indication to reflect the location of SOLICITED PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 22:38:03

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
User entered 'SOLICITED PAIN'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 14:37:42

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '500'	Melissa Fuson (b) (4)	26 Oct 2020 14:37:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'mg (mg)'	Melissa Fuson (b) (4)	26 Oct 2020 14:37:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:32

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 14:37:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'as needed (PRN)'	Melissa Fuson (b) (4)	26 Oct 2020 14:37:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 14:37:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'Oral (ORAL)'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 14:37:42

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 14:37:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'UN Sep 2020'	Melissa Fuson (b) (4)	26 Oct 2020 14:37:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	26 Oct 2020 14:37:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	26 Oct 2020 14:37:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 14:37:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	26 Oct 2020 14:37:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 14:37:42

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 14:37:42

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 14:37:42

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	26 Oct 2020 20:26:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 20:26:31
Data point term sent to Coder	System	26 Oct 2020 14:39:37
User entered 'CLARITION -'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 14:38:51

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 14:38:51

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'ALLERGIC RHINTIS - SEASONAL'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 14:38:51

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered '10'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 14:38:51

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'mg (mg)'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 14:38:51

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 14:38:51
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'once daily (QD)'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 14:38:51

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 14:38:51
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'Oral (ORAL)'	(b) (4) Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 14:38:51

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 14:38:51
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'UN UNK 2018'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 14:38:51

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered '0'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 14:38:51

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 14:38:51

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 14:38:51
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 14:38:51

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 14:38:51

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 14:38:51

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Oct 2020 14:38:51

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
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 Dec 2020 14:22:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 14:22:22
Data point term sent to Coder	System	29 Dec 2020 13:40:25
User entered 'FLU VACCINE'	Melissa Fuson (b) (4)	29 Dec 2020 13:39:36

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 13:39:36

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'GENERAL HEALTH FLU PREVENTION'	Melissa Fuson (b) (4)	29 Dec 2020 13:39:36

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered '0.5'	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 13:39:36

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'mL (mL)'	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 13:39:36

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered empty.	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 13:39:36

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'once (ONCE)'	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 13:39:36

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered empty.	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 13:39:36

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 13:39:36

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered empty.	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 13:39:36

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered '05 Nov 2020'	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 13:39:36

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered '0'	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 13:39:36

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 13:39:36

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered '05 Nov 2020'	Melissa Fuson (b) (4)	29 Dec 2020 13:39:36

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 13:39:36

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:15
User entered empty.	System	29 Dec 2020 13:39:36

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:15
User entered empty.	System	29 Dec 2020 13:39:36

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:15
User entered empty.	System	29 Dec 2020 13:39:36

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 20:55:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 20:55:12
Data point term sent to Coder	System	29 Mar 2021 20:54:50
User entered 'flonase'	Andrea Newlands (b) (4)	29 Mar 2021 20:54:15

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 20:54:15

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'seasonal allergies'	Andrea Newlands (b) (4)	29 Mar 2021 20:54:15

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered '2'	Andrea Newlands (b) (4)	29 Mar 2021 20:54:15

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'puff (PUFF)'	(b) (4) Andrea Newlands (b) (4)	29 Mar 2021 20:54:15

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered empty.	(b) (4)	29 Mar 2021 20:54:15
	Andrea Newlands (b) (4)	
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	29 Mar 2021 20:54:15

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered empty.	(b) (4)	29 Mar 2021 20:54:15
	Andrea Newlands (b) (4)	
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Andrea Newlands (b) (4)	29 Mar 2021 20:54:15

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered empty.	(b) (4)	29 Mar 2021 20:54:15
	Andrea Newlands (b) (4)	
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'un UNK 2010'	Andrea Newlands (b) (4)	29 Mar 2021 20:54:15

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered '0'	Andrea Newlands (b) (4)	29 Mar 2021 20:54:15

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'Yes (Y)'	(b) (4) Andrea Newlands (b) (4)	29 Mar 2021 20:54:15

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered empty.	(b) (4)	29 Mar 2021 20:54:15

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 20:54:15

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:17
User entered empty.	System	29 Mar 2021 20:54:15

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:17
User entered empty.	System	29 Mar 2021 20:54:15

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:17
User entered empty.	System	29 Mar 2021 20:54:15

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:11
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 19:47:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 19:47:12
Data point term sent to Coder	System	14 Apr 2021 19:46:16
Coding entries removed.	Steven Anderson (b) (4)	14 Apr 2021 19:45:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 21:04:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 21:04:11
Data point term sent to Coder	System	29 Mar 2021 21:03:06
User entered 'miralax'	Andrea Newlands (b) (4)	29 Mar 2021 21:03:03

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:11
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	14 Apr 2021 19:45:45
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 21:03:03

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:11
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 09:12:20
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. answered with 'this has been updated it was only being used as a prophylactic after her surgery' (Site from DM).	Steven Anderson (b) (4)	14 Apr 2021 19:46:17
User entered 'CONSTIPATION prophylactic' reason for change: Data Entry Error	Steven Anderson (b) (4)	14 Apr 2021 19:45:45
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 12:00:50
User entered 'constipation'	Andrea Newlands (b) (4)	29 Mar 2021 21:03:03

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:11
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered '17'	Andrea Newlands (b) (4)	29 Mar 2021 21:03:03

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:11
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'g (g)'	Andrea Newlands (b) (4)	29 Mar 2021 21:03:03

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:11
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 21:03:03

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:11
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'once daily (QD)'	Andrea Newlands (b) (4)	29 Mar 2021 21:03:03

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:11
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 21:03:03

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:11
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	29 Mar 2021 21:03:03

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:11
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 21:03:03

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:11
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered '25 Feb 2021'	Andrea Newlands (b) (4)	29 Mar 2021 21:03:03

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:11
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered '0'	Andrea Newlands (b) (4)	29 Mar 2021 21:03:03

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:11
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:24:20
User closed query 'Please confirm if this medication is ongoing and update as appropriate' (Site from CRA).		21 Apr 2021 18:54:47
Query 'Please confirm if this medication is ongoing and update as appropriate' answered with 'this has been updated' (Site from CRA).	Steven Anderson (b) (4)	21 Apr 2021 18:37:30
Signature has been broken.	Steven Anderson (b) (4)	21 Apr 2021 18:37:23
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 18:37:23
User opened query 'Please confirm if this medication is ongoing and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 13:52:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	29 Mar 2021 21:03:03

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:11
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:24:20
Signature has been broken.	Steven Anderson (b) (4)	21 Apr 2021 18:37:23
User entered '16 Mar 2021' reason for change: Data Entry Error	(b) (4) Steven Anderson (b) (4)	21 Apr 2021 18:37:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered empty.	(b) (4) Andrea Newlands (b) (4)	29 Mar 2021 21:03:03

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:11
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 21:03:03

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:11
User entered '1'	System	29 Mar 2021 21:03:03

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:11
User entered '1'	System	29 Mar 2021 21:03:03

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:11
User entered '804 (804)'	System	29 Mar 2021 21:03:03

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:45:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Mar 2021 09:00:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 09:00:27
Data point term sent to Coder	System	29 Mar 2021 21:04:07
User entered 'oxycodone'	Andrea Newlands (b) (4) (b) (4)	29 Mar 2021 21:03:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:45:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 21:03:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:45:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'hip fracture pain'	Andrea Newlands (b) (4)	29 Mar 2021 21:03:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:45:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4)	16 Apr 2021 09:14:09
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 17:10:45
User entered '5' reason for change: Data Entry Error		14 Apr 2021 17:10:27
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).		07 Apr 2021 12:12:52
User entered '.5'	Andrea Newlands (b) (4)	29 Mar 2021 21:03:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:45:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'mg (mg)'	Andrea Newlands (b) (4)	29 Mar 2021 21:03:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:45:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 21:03:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:45:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	29 Mar 2021 21:03:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:45:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 21:03:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:45:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	29 Mar 2021 21:03:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:45:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 21:03:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:45:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered '22 Feb 2021'	Andrea Newlands (b) (4)	29 Mar 2021 21:03:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:45:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered '0'	Andrea Newlands (b) (4)	29 Mar 2021 21:03:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:45:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 21:03:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:45:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered '01 Mar 2021'	Andrea Newlands (b) (4)	29 Mar 2021 21:03:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:45:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 21:03:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:17
User entered empty.	System	29 Mar 2021 21:03:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:17
User entered empty.	System	29 Mar 2021 21:03:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:17
User entered empty.	System	29 Mar 2021 21:03:47

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:32

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:48:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Mar 2021 08:23:35
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Mar 2021 08:23:35
	(b) (4)	
Data point term sent to Coder	System	29 Mar 2021 21:05:15
User entered 'tramadol'	Andrea Newlands (b) (4)	29 Mar 2021 21:04:19
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:32

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:48:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 21:04:19
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:48:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'hip fracture pain'	Andrea Newlands (b) (4)	29 Mar 2021 21:04:19
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:32

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:48:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '50'	Andrea Newlands (b) (4)	29 Mar 2021 21:04:19
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:32

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:48:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'mg (mg)'	Andrea Newlands (b) (4)	29 Mar 2021 21:04:19
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:32

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:48:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 21:04:19
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:32

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:48:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	29 Mar 2021 21:04:19
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:32

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:48:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 21:04:19
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:32

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:48:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	29 Mar 2021 21:04:19
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:32

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:48:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 21:04:19
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:48:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '01 Mar 2021'	Andrea Newlands (b) (4)	29 Mar 2021 21:04:19
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:48:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	29 Mar 2021 21:04:19
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:32

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:48:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 21:04:19
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:48:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '29 Mar 2021'	Andrea Newlands (b) (4)	29 Mar 2021 21:04:19
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:48:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 21:04:19
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 21:04:19

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 21:04:19

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 21:04:19

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: DOCUSATE SODIUM;SENNOSIDE A+B, PRODUCTSYNONYM: SENNA-S [DOCUSATE SODIUM;SENNOSIDE A+B] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 07:17:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 07:17:57
Data point term sent to Coder	System	14 Apr 2021 19:48:19
Coding entries removed.	Steven Anderson (b) (4)	14 Apr 2021 19:48:14
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: DOCUSATE SODIUM;SENNOSIDE A+B, PRODUCTSYNONYM: SENNA S - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 18:21:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 18:21:59
Data point term sent to Coder	System	12 Apr 2021 17:08:11
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' canceled (Site from System).	Coder Import (b) (4)	12 Apr 2021 17:08:06

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:32

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	01 Apr 2021 08:44:28
Data point term sent to Coder	System	29 Mar 2021 21:06:18
User entered 'senna-s'	Andrea Newlands (b) (4)	29 Mar 2021 21:05:29
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	14 Apr 2021 19:49:19
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 21:05:29

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 08:41:17
(Site from DM).		
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.'	Steven Anderson (b) (4)	14 Apr 2021 19:49:54
' answered with 'this has been updated it was only being used as a prophylactic after her surgery' (Site from DM).	(b) (4)	
User entered 'CONSTIPATION prophylactic' reason for change: Data Entry Error	Steven Anderson (b) (4)	14 Apr 2021 19:48:14
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.'	(b) (4), (b) (6)	07 Apr 2021 12:13:12
(Site from DM).		
User entered 'constipation'	Andrea Newlands (b) (4)	29 Mar 2021 21:05:29
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered '8.6/50'	Andrea Newlands (b) (4)	29 Mar 2021 21:05:29

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'mg (mg)'	Andrea Newlands (b) (4)	29 Mar 2021 21:05:29

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 21:05:29

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'twice daily (BID)'	Andrea Newlands (b) (4)	29 Mar 2021 21:05:29

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 21:05:29

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	29 Mar 2021 21:05:29

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 21:05:29

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered '22 Feb 2021'	Andrea Newlands (b) (4)	29 Mar 2021 21:05:29

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered '0'	Andrea Newlands (b) (4)	29 Mar 2021 21:05:29

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:22:31
User closed query 'Please confirm if this medication is ongoing and update as appropriate' (Site from CRA).		21 Apr 2021 20:21:59
Query 'Please confirm if this medication is ongoing and update as appropriate' answered with 'this has been updated ' (Site from CRA).	Steven Anderson (b) (4)	21 Apr 2021 18:37:58
Signature has been broken.	Steven Anderson (b) (4)	21 Apr 2021 18:37:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Steven Anderson (b) (4)	21 Apr 2021 18:37:49
User opened query 'Please confirm if this medication is ongoing and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 13:53:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'Yes (Y)'	(b) (4) Andrea Newlands (b) (4)	29 Mar 2021 21:05:29

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:22:31
Signature has been broken.	Steven Anderson (b) (4)	21 Apr 2021 18:37:49
User entered '16 Mar 2021' reason for change: Data Entry Error	(b) (4) Steven Anderson (b) (4)	21 Apr 2021 18:37:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered empty.	(b) (4) Andrea Newlands (b) (4)	29 Mar 2021 21:05:29

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 21:05:29

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:23
User entered '2'	System	29 Mar 2021 21:05:29

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:23
User entered '1'	System	29 Mar 2021 21:05:29

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:23
User entered '804 (804)'	System	29 Mar 2021 21:05:29

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:32

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
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.	Coder Import (b) (4)	29 Mar 2021 21:07:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 21:07:35
	(b) (4)	
Data point term sent to Coder	System	29 Mar 2021 21:06:17
User entered 'tylenol'	Andrea Newlands (b) (4)	29 Mar 2021 21:06:12
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:32

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 21:06:12
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'hip fracture pain'	Andrea Newlands (b) (4)	29 Mar 2021 21:06:12
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:32

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '650'	Andrea Newlands (b) (4)	29 Mar 2021 21:06:12
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:32

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'mg (mg)'	Andrea Newlands (b) (4)	29 Mar 2021 21:06:12
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:32

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 21:06:12
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:32

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	29 Mar 2021 21:06:12
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 21:06:12
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:32

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	29 Mar 2021 21:06:12
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:32

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 21:06:12
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '22 Feb 2021'	Andrea Newlands (b) (4)	29 Mar 2021 21:06:12
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	29 Mar 2021 21:06:12
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:26:32
User closed query 'Please confirm if this medication is ongoing and update as appropriate' (Site from CRA).		21 Apr 2021 20:25:58
Query 'Please confirm if this medication is ongoing and update as appropriate' answered with 'this has been updated' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:38:21
Signature has been broken.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:38:14
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:38:14
User opened query 'Please confirm if this medication is ongoing and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 13:52:40
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 13:33:17
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	29 Mar 2021 21:06:12

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:26:32
Signature has been broken.	Steven Anderson (b) (4)	21 Apr 2021 18:38:14
User entered '01 Apr 2021' reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Steven Anderson (b) (4)	21 Apr 2021 18:38:14
	(b) (4)	
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 21:06:12
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 21:06:12
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 21:06:12

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 21:06:12

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 21:06:12

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Apr 2021 19:59:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 19:59:13
Data point term sent to Coder	System	21 Apr 2021 18:47:57
User entered 'melatonin'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:47:42

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	21 Apr 2021 18:47:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
	(b) (4)	
User entered 'insomnia'	Steven Anderson (b) (4)	21 Apr 2021 18:47:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
	(b) (4)	
User entered '3'	Steven Anderson (b) (4)	21 Apr 2021 18:47:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
	(b) (4)	
User entered 'mg (mg)'	Steven Anderson (b) (4)	21 Apr 2021 18:47:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	21 Apr 2021 18:47:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
	(b) (4)	
User entered 'as needed (PRN)'	Steven Anderson (b) (4)	21 Apr 2021 18:47:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	21 Apr 2021 18:47:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
	(b) (4)	
User entered 'Oral (ORAL)'	Steven Anderson (b) (4)	21 Apr 2021 18:47:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	21 Apr 2021 18:47:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:32

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
	(b) (4)	
User entered '25 Feb 2021'	Steven Anderson (b) (4)	21 Apr 2021 18:47:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
	(b) (4)	
User entered '0'	Steven Anderson (b) (4)	21 Apr 2021 18:47:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
	(b) (4)	
User entered 'Yes (Y)'	Steven Anderson (b) (4)	21 Apr 2021 18:47:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	21 Apr 2021 18:47:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	21 Apr 2021 18:47:42
	(b) (4)	

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 18:47:42

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 18:47:42

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 18:47:42

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 07:32:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 07:32:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:06
Data point term sent to Coder	System	21 Apr 2021 18:50:01
User entered 'xeralto'	Steven Anderson (b) (4)	21 Apr 2021 18:49:07

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:28:06
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:49:07

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:28:06
User entered 'DVT prophylaxis from surgery'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:49:07

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:28:06
User entered '10'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:49:07

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:28:06
User entered 'mg (mg)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:49:07

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:28:06
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:49:07

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:28:06
User entered 'once daily (QD)'	Steven Anderson (b) (4)	21 Apr 2021 18:49:07

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:28:06
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:49:07

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:28:06
User entered 'Oral (ORAL)'	Steven Anderson (b) (4)	21 Apr 2021 18:49:07

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:28:06
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:49:07

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:28:06
User entered '25 Feb 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:49:07

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:28:06
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:49:07

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:28:06
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:49:07

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:28:06
User entered '11 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:49:07

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:28:06
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:49:07

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:47
User entered '1'	System	21 Apr 2021 18:49:07

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:47
User entered '1'	System	21 Apr 2021 18:49:07

US3412337

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:47
User entered '804 (804)'	System	21 Apr 2021 18:49:07

US3412337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:31:32

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:50
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
User closed query 'Per ETRTR, According to Left Hip Fracture SAE, concomitant procedures were done. Please reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:31:57
Query 'Per ETRTR, According to Left Hip Fracture SAE, concomitant procedures were done. Please reconcile.' answered with 'this has been updated and con procedure has been added' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	14 Apr 2021 15:25:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	14 Apr 2021 15:24:20
User opened query 'Per ETRTR, According to Left Hip Fracture SAE, concomitant procedures were done. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 00:12:16
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 17:20:37

US3412337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:31:32

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:41:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered '23 Feb 2021'	Steven Anderson (b) (4)	14 Apr 2021 15:26:52
	(b) (4)	

US3412337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:31:32

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:41:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'intramedullary nail fixation femur fracture'	Steven Anderson (b) (4)	14 Apr 2021 15:26:52
	(b) (4)	

US3412337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:41:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4)	14 Apr 2021 15:26:52
	(b) (4)	

US3412337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:31:32

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:41:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	14 Apr 2021 15:26:52
	(b) (4)	

US3412337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:31:32

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:41:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered '23 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 16:21:18

US3412337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:31:32

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:41:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'chest x-ray'	(b) (4), (b) (6)	15 Apr 2021 16:21:18

US3412337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:41:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	15 Apr 2021 16:21:18

US3412337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:31:32

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:41:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 16:21:18

US3412337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:31:32

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:41:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered '23 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 16:21:43

US3412337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:31:32

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:41:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'X-ray left hip'	(b) (4), (b) (6)	15 Apr 2021 16:21:43

US3412337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:31:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:41:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	15 Apr 2021 16:21:43

US3412337

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:31:32

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:39:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:41:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:33:17
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 16:21:43

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered		
'USA-US061-2021-MRNA-1273-P301000010'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'Yes (Y)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'No (N)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'No (N)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'Yes (Y)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'No (N)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'No (N)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'No (N)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 16:19:49
User entered 'Richard'	System	15 Apr 2021 16:19:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'Gregory'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 16:19:49
User entered 'Powell'	System	15 Apr 2021 16:19:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'Gottschlich'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 16:19:49
User entered empty.	System	15 Apr 2021 16:19:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered '4260 Glendale Milford Road'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 16:19:49
User entered empty.	System	15 Apr 2021 16:19:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'Cincinnati'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered 'OH'	(b) (4) System	15 Apr 2021 16:19:49

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 16:19:49
User entered empty.	System	15 Apr 2021 16:19:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered '45242'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'US'	System	25 Feb 2021 17:25:35

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 14:35:36
User entered '2'	System	15 Apr 2021 16:19:49
User entered '1'	System	25 Feb 2021 17:25:35

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'USA-US061-2021-MRNA-1273-P301000010'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'Yes (Y)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'No (N)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'No (N)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'Yes (Y)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'No (N)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'No (N)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'No (N)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 16:19:49
User entered 'Richard'	System	15 Apr 2021 16:19:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'Gregory'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 16:19:49
User entered 'Powell'	System	15 Apr 2021 16:19:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'Gottschlich'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 16:19:49
User entered empty.	System	15 Apr 2021 16:19:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered '4260 Glendale Milford Road'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 16:19:49
User entered empty.	System	15 Apr 2021 16:19:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'Cincinnati'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered 'OH'	(b) (4) System	15 Apr 2021 16:19:49

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 16:19:49
User entered empty.	System	15 Apr 2021 16:19:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered '45242'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'US'	System	25 Feb 2021 17:25:35

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 14:35:36
User entered '2'	System	15 Apr 2021 16:19:49
User entered '1'	System	25 Feb 2021 17:25:35

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:31:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered '25/Feb/2021 11:25'	(b) (4) System	25 Feb 2021 17:25:35

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:31:32

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.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'I'		25 Feb 2021 17:25:35

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'USA-US061-2021-MRNA-1273-P301000010'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'Yes (Y)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'No (N)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'No (N)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'Yes (Y)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'No (N)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'No (N)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'No (N)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 16:19:49
User entered 'Richard'	System	15 Apr 2021 16:19:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'Gregory'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 16:19:49
User entered 'Powell'	System	15 Apr 2021 16:19:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'Gottschlich'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 16:19:49
User entered empty.	System	15 Apr 2021 16:19:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered '4260 Glendale Milford Road'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 16:19:49
User entered empty.	System	15 Apr 2021 16:19:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'Cincinnati'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered 'OH'	(b) (4) System	15 Apr 2021 16:19:49

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 16:19:49
User entered empty.	System	15 Apr 2021 16:19:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered '45242'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'US'	System	25 Feb 2021 17:25:35

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 14:35:36
User entered '2'	System	15 Apr 2021 16:19:49
User entered '1'	System	25 Feb 2021 17:25:35

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:31:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered '15/Apr/2021 12:19'	(b) (4) System	15 Apr 2021 16:19:49

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:31:32

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)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:19:49

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered		
'USA-US061-2021-MRNA-1273-P301000010'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'Yes (Y)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'No (N)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'No (N)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'Yes (Y)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'No (N)'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'No (N)'	System	25 Feb 2021 17:24:56

US3412337

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'No (N)'	System	25 Feb 2021 17:24:56

US3412337

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 16:19:49
User entered 'Richard'	System	15 Apr 2021 16:19:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'Gregory'	System	25 Feb 2021 17:24:56

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 16:19:49
User entered 'Powell'	System	15 Apr 2021 16:19:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'Gottschlich'	System	25 Feb 2021 17:24:56

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[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 16:19:49
User entered empty.	System	15 Apr 2021 16:19:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered '4260 Glendale Milford Road'	System	25 Feb 2021 17:24:56

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Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 16:19:49
User entered empty.	System	15 Apr 2021 16:19:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'Cincinnati'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

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[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
User entered 'OH'	(b) (4) System	15 Apr 2021 16:19:49

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[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 16:19:49
User entered empty.	System	15 Apr 2021 16:19:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered '45242'	System	25 Feb 2021 17:24:56

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	18 Apr 2021 21:32:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:25:40
User entered 'US'	System	25 Feb 2021 17:25:35

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Folder: SAE USA-US061-2021-MRNA-1273-P301000010

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 14:35:36
User entered '2'	System	15 Apr 2021 16:19:49
User entered '1'	System	25 Feb 2021 17:25:35

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

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[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
User entered '22/Apr/2021 10:35'	(b) (4) System	22 Apr 2021 14:35:36

US3412337

Folder: SAE USA-US061-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

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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.	Richard Powell (b) (4)	26 Apr 2021 14:44:50
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:35:46
User entered 'I'		22 Apr 2021 14:35:36