

US3312434 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:02:25

All time stamps listed in this document are displayed in GMT

US3312434

Form: Participant Creation

Data signed: (b) (4) 06 Apr 2021 02:32:57

Generated On: 09 Jun 2021 17:02:25

Participant ID

US3312434

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

US3312434

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 22:48:00

Generated On: 09 Jun 2021 17:02:25

Date of Birth (MMM yyyy)	(b) (6) 1951
Age	69
Age Units	YEARS
Age (Derived)	69
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) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

Date of Informed Consent (<i>dd MMM yyyy</i>)	1 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" 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) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

Condition	OSTEOARTHRITIS LEFT KNEE
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) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

Condition	OSTEOPOROSIS
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

Condition	POST MENOPAUSAL
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) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

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

US3312434

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 SEP 2020
Time of assessment (00:00-23:59)	12:06 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 12:06
Height (xxx.x)	67 in
Weight (xxx.x)	129 lb
BMI (xxx.x)	20.24650 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 SEP 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) 15 Feb 2021 22:48:00

Generated On: 09 Jun 2021 17:02:25

Date of assessment (dd MMM yyyy) 01 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:48:01

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:48:01

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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)	False
Other	True
Specify	RESIDES IN COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

What was the date of randomization? (dd MMM yyyy) 01 SEP 2020

What was the participant's randomization number? 189425

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) 15 Feb 2021 22:48:01

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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) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

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)	01 SEP 2020
Time of assessment (00:00-23:59)	12:06 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 12:06
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

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)	01 SEP 2020
Time of assessment (00:00-23:59)	13:55 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 13:55
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

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) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

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) 1 SEP 2020

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

Treatment Date and Time (derived) 1 SEP 2020 13:24

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) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 SEP 2020
Collection time (00:00-23:59)	12:46 (24 HR)
Collection date and time (derived)	01 SEP 2020 12:46

US3312434

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

Collection date (dd MMM yyyy)			01 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:38	01 SEP 2020 12:38
Nasopharyngeal Swab 2	No		

US3312434

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

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 17:02:25

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

98.5 °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

01 SEP 2020 14:04

PC Open Date & Time

01 SEP 2020 13:44

PC Close Date & Time

01 SEP 2020 16:14

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

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 97.9 °F

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

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

PC Time Stamp	01 SEP 2020 17:17
PC Open Date & Time	01 SEP 2020 17:09
PC Close Date & Time	02 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:25

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

97.6 °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

02 SEP 2020 17:44

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:25

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

97.6 °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

03 SEP 2020 15:24

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:25

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 15:52

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:25

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

97.4 °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 20:49

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:25

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

97.7 °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

06 SEP 2020 14:37

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:25

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

97.7 °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

07 SEP 2020 17:58

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 14:05

PC Open Date & Time

01 SEP 2020 13:44

PC Close Date & Time

01 SEP 2020 16:14

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

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

01 SEP 2020 17:18

PC Open Date & Time

01 SEP 2020 17:09

PC Close Date & Time

02 SEP 2020 11:59

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:25

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

02 SEP 2020 17:44

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:25

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

03 SEP 2020 15:25

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:25

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

04 SEP 2020 15:52

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:25

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

05 SEP 2020 20:50

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:25

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

06 SEP 2020 14:37

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:25

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

07 SEP 2020 17:58

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 14:06
PC Open Date & Time	01 SEP 2020 13:44
PC Close Date & Time	01 SEP 2020 16:14

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 17:19
PC Open Date & Time	01 SEP 2020 17:09
PC Close Date & Time	02 SEP 2020 11:59

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

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 ☒

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 17:45
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 15:25
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 15:53
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

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

53 of 2612

EAB) (1725)

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 20:50
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

55 of 2612

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 14:37
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

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

57 of 2612

EAB) (1725)

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 17:59
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3312434

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:48:00

Generated On: 09 Jun 2021 17:02:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312434

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:48:00

Generated On: 09 Jun 2021 17:02:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312434

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:48:00

Generated On: 09 Jun 2021 17:02:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312434

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:48:00

Generated On: 09 Jun 2021 17:02:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312434

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:48:00

Generated On: 09 Jun 2021 17:02:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312434

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:48:00

Generated On: 09 Jun 2021 17:02:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312434

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

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)	29 SEP 2020
Time of assessment (00:00-23:59)	11:37 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 11:37
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	168 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	13:26 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 13:26
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3312434

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3312434

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

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) 29 SEP 2020

What was the treatment time? (00:00-23:59) 12:55 (24 HR)

Treatment Date and Time (derived) 29 SEP 2020 12:55

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

US3312434

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 SEP 2020
Collection time (00:00-23:59)	12:10 (24 HR)
Collection date and time (derived)	29 SEP 2020 12:10

US3312434

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

Collection date (dd MMM yyyy)			29 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:58	29 SEP 2020 11:58
Nasopharyngeal Swab 2	No		

US3312434

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

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

97.8 °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

29 SEP 2020 13:29

PC Open Date & Time

29 SEP 2020 13:15

PC Close Date & Time

29 SEP 2020 15:45

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

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 97.8 °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	29 SEP 2020 18:21
PC Open Date & Time	29 SEP 2020 16:40
PC Close Date & Time	30 SEP 2020 11:59

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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 18:28

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:25

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

97.8 °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 17:11

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 18:13

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:25

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

97.6 °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

03 OCT 2020 16:43

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:25

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

97.5 °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

04 OCT 2020 15:50

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:25

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

05 OCT 2020 14:57

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

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

29 SEP 2020 13:29

PC Open Date & Time

29 SEP 2020 13:15

PC Close Date & Time

29 SEP 2020 15:45

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

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

29 SEP 2020 18:21

PC Open Date & Time

29 SEP 2020 16:40

PC Close Date & Time

30 SEP 2020 11:59

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:25

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

30 SEP 2020 18:28

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:25

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

01 OCT 2020 17:11

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:25

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

02 OCT 2020 18:13

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:25

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

03 OCT 2020 16:43

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:25

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

04 OCT 2020 15:50

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:25

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

05 OCT 2020 14:57

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 13:29
PC Open Date & Time	29 SEP 2020 13:15
PC Close Date & Time	29 SEP 2020 15:45

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 18:22
PC Open Date & Time	29 SEP 2020 16:40
PC Close Date & Time	30 SEP 2020 11:59

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 18:28
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

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 ☒

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 17:12
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

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

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EAB) (1725)

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 18:14
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 16:44
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

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 ☒

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 15:51
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

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 ☒

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EAB) (1725)

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 14:58
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3312434

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:48:00

Generated On: 09 Jun 2021 17:02:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312434

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:48:00

Generated On: 09 Jun 2021 17:02:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312434

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:48:00

Generated On: 09 Jun 2021 17:02:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312434

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:48:00

Generated On: 09 Jun 2021 17:02:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312434

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:48:00

Generated On: 09 Jun 2021 17:02:25

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 20 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3312434

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:48:00

Generated On: 09 Jun 2021 17:02:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312434

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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

US3312434

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	11:10 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 11:10
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312434

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

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.

US3312434

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 OCT 2020
Collection time (00:00-23:59)	11:25 (24 HR)
Collection date and time (derived)	27 OCT 2020 11:25

US3312434

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:48:01

Generated On: 09 Jun 2021 17:02:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312434

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 NOV 2020 06:14:59

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3312434

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 NOV 2020 08:57:52

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3312434

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 07:34:18

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 <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"/>

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 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"/>

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2020 00:01
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Patient Cloud Close Date & Time	30 NOV 2020 23:59
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US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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	03 DEC 2020 07:27:09
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

10 DEC 2020 06:36:15

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	17 DEC 2020 07:12:13
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 117

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

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

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

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

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

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

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

31 DEC 2020 07:20:39

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

14 JAN 2021 06:48:13

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

21 JAN 2021 06:33:22

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

28 JAN 2021 06:50:03

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

04 FEB 2021 08:43:05

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 <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	11 FEB 2021 07:05:10
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

18 FEB 2021 08:43:51

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 FEB 2021 14:14:33
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

04 MAR 2021 07:15:09

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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	12 MAR 2021 12:00:17
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

18 MAR 2021 06:59:54

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

25 MAR 2021 06:46:01

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

01 APR 2021 06:52:50

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

08 APR 2021 09:34:51

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

18 APR 2021 08:07:56

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

22 APR 2021 06:54:00

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 07:00:07

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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"/>

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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°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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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"/>

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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°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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

Patient Cloud Open Date & Time	19 AUG 2021 00:01
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Patient Cloud Close Date & Time	23 AUG 2021 23:59
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US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 404

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

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

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

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

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

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

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2021 00:01
Patient Cloud Close Date & Time	11 OCT 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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"/>

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 418

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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°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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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"/>

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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"/>

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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°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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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"/>

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 467

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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"/>

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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"/>

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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"/>

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 670

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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°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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 712

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 719

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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"/>

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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"/>

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

Date and time of submission

Patient Cloud Open Date & Time	20 OCT 2022 00:01
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Patient Cloud Close Date & Time	24 OCT 2022 23:59
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US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	27 OCT 2022 00:01
Patient Cloud Close Date & Time	31 OCT 2022 23:59

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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"/>

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3312434

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:02:25

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 17:50:34

US3312434

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312434

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312434

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312434

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312434

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312434

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312434

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312434

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312434

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

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

Visit date (dd MMM yyyy)	19 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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US3312434

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

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) _____

US3312434

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

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.

US3312434

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

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

Collection date (dd MMM yyyy)	19 MAR 2021
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Collection time (00:00-23:59)	10:49 (24 HR)
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Collection date and time (derived)	19 MAR 2021 10:49
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US3312434

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312434

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

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

US3312434

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312434

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:02:25

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"/>

US3312434

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:02:25

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3312434

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

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

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

Visit date (dd MMM yyyy)	11 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3312434

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

Form: Unblinding

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

Date of updated informed consent (<i>dd MMM yyyy</i>)	11 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	11 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3312434

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

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

US3312434

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 JAN 2021
Time of assessment (00:00-23:59)	13:12 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 13:12
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3312434

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 JAN 2021
Time of assessment (00:00-23:59)	14:35 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 14:35
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3312434

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

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 JAN 2021

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

US3312434

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

Form: Exposure

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

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

What was the treatment time? (00:00-23:59) 14:04 (24 HR)

Treatment Date and Time (derived) 11 JAN 2021 14:04

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

US3312434

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 JAN 2021

Collection time (00:00-23:59)

13:00 (24 HR)

Collection date and time (derived)

11 JAN 2021 13:00

US3312434

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00 - 23:59)	12:59
Collection Date and Time (derived)	11 JAN 2021 12:59

US3312434

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

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312434

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312434

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

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

US3312434

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

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)	19 FEB 2021
Time of assessment (00:00-23:59)	09:36 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 09:36
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

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)	19 FEB 2021
Time of assessment (00:00-23:59)	11:06 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 11:06
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	56 mmHg
Diastolic Blood Pressure units	MMHG

US3312434

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 FEB 2021

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

US3312434

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 06 Apr 2021 02:32:57

Generated On: 09 Jun 2021 17:02:25

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 19 FEB 2021

What was the treatment time? (00:00-23:59) 10:35 (24 HR)

Treatment Date and Time (derived) 19 FEB 2021 10:35

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

US3312434

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 02:32:57

Generated On: 09 Jun 2021 17:02:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312434

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312434

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312434

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3312434

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

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) _____

US3312434

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

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.

US3312434

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 MAR 2021
Collection time (00:00-23:59)	10:49 (24 HR)
Collection date and time (derived)	19 MAR 2021 10:49

US3312434

Folder: Unscheduled 01 Sep 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

Visit Date	01 SEP 2020
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3312434

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 SEP 2020
Time of assessment (00:00-23:59)	14:00 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 14:00
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

Visit Date	29 SEP 2020
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	11:47 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 11:47
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

Visit Date	29 SEP 2020
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 02:33:29

Generated On: 09 Jun 2021 17:02:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	13:31 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 13:31
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312434

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 16:01:37

Generated On: 09 Jun 2021 17:02:25

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3312434

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

AEID

Adverse event

NASAL CONGESTION

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

10 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312434

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

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

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

AEID

Adverse event

RUNNY NOSE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

10 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

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

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

AEID

Adverse event

ELEVATED SYSTOLIC BLOOD
PRESSURE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

29 SEP 2020

Start time (00:00-23:59)

11:37 (24 HR)

AE start date and time (derived)

29 SEP 2020 11:37

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

27 OCT 2020

End time (00:00-23:59)

11:17 (24 HR)

AE End Date and Time (derived)

27 OCT 2020 11:17

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

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

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

AEID

Adverse event

IDIOPATHIC AVASCULAR
NECROSIS RIGHT HIP

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

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 <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3312434

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

AEID	USA-US300-2021-MRNA-1273-P30 1000017
Adverse event	WORSENING OSTEOARTHRITIS RIGHT HIP
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)	15 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	03 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	01 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	03 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

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 <input type="radio"/>
	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	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

PLEASE NOTE THAT THE
SOURCE OF INFORMATION FOR
THIS SAE REPORT IS THE
SUBJECT'S VERBAL REPORT.
SUBJECT, AT HER OPEN LABEL
D29 VISIT, REPORTED RIGHT
TOTAL HIP REPLACEMENT
WITH POST-OPERATIVE
HOSPITALIZATION DUE TO END
STAGE OSTEOARTHRITIS WITH
AVASCULAR NECROSIS OF
RIGHT HIP. SUBJECT IS A 70
YEAR OLD FEMALE WITH H/O
HTN, OSTEOPOROSIS AND
OSTEOARTHRITIS AT
SCREENING; SHE WAS LATER
DIAGNOSED WITH IDIOPATHIC
AVASCULAR NECROSIS OF THE
RIGHT HIP ON 10/15/2020. THE
OSTEOARTHRITIS WAS
INITIALLY REPORTED TO
INVOLVE THE LEFT KNEE BUT
IS NOW BELIEVED THAT LEFT
KNEE PAIN WAS RELATED TO
RIGHT HIP OSTEOARTHRITIS
WITH AVASCULAR NECROSIS.
RIGHT TOTAL HIP
REPLACEMENT TOOK PLACE
ON 2/1/21 AND SHE WAS
HOSPITALIZED
POST-OPERATIVELY FROM
2/1/21—2/3/21. HER
POST-OPERATIVE COURSE WAS
COMPLICATED BY ANEMIA
(HEMOGLOBIN DROPPED TO

US3312434

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

8MG/DL RANGE) BUT SHE DID NOT REQUIRE TRANSFUSION. SHE REMAINED IN HOSPITAL FOR OBSERVATION AN EXTRA NIGHT FOR MONITORING OF ANEMIA. SHE WAS DISCHARGED ON PRN OXYCODONE (DOSE UNKNOWN) WHICH SHE TOOK FOR THE FIRST WEEK AND PRN TYLENOL 1000MG WHICH SHE STILL TAKES ON OCCASION BUT REPORTS TO BE RECOVERING NICELY AND IS ABOUT 80% BACK TO BASELINE. SHE WILL CONTINUE TO FOLLOW WITH HER ORTHOPEDIC SURGEON, NEXT FOLLOW-UP SCHEDULED 3/16/21. THIS IS AN SAE OF END STAGE OSTEOARTHRITIS WITH AVASCULAR NECROSIS OF THE RIGHT HIP JOINT REQUIRING HOSPITALIZATION FOR TOTAL HIP REPLACEMENT, NOT RELATED TO IP. THIS IS ALSO AND SAE OF PROLONGED HOSPITALIZATION RELATED TO POST-OPERATIVE ANEMIA, NOT RELATED TO IP. MEDICAL RECORDS ARE BEING REQUESTED. FOLLOW UP 24FEB2021: EMAIL SENT TO SAFETY TEAM AS NOT ENOUGH CHARACTERS TO

US3312434

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

AEID	USA-US300-2021-MRNA-1273-P30 1000017
Adverse event	POST OPERATIVE ANEMIA
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)	02 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)	03 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	01 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	03 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

PLEASE NOTE THAT THE
SOURCE OF INFORMATION FOR
THIS SAE REPORT IS THE
SUBJECT'S VERBAL REPORT.
SUBJECT, AT HER OPEN LABEL
D29 VISIT, REPORTED RIGHT
TOTAL HIP REPLACEMENT
WITH POST-OPERATIVE
HOSPITALIZATION DUE TO END
STAGE OSTEOARTHRITIS WITH
AVASCULAR NECROSIS OF
RIGHT HIP. SUBJECT IS A 70
YEAR OLD FEMALE WITH H/O
HTN, OSTEOPOROSIS AND
OSTEOARTHRITIS AT
SCREENING; SHE WAS LATER
DIAGNOSED WITH IDIOPATHIC
AVASCULAR NECROSIS OF THE
RIGHT HIP ON 10/15/2020. THE
OSTEOARTHRITIS WAS
INITIALLY REPORTED TO
INVOLVE THE LEFT KNEE BUT
IS NOW BELIEVED THAT LEFT
KNEE PAIN WAS RELATED TO
RIGHT HIP OSTEOARTHRITIS
WITH AVASCULAR NECROSIS.
RIGHT TOTAL HIP
REPLACEMENT TOOK PLACE
ON 2/1/21 AND SHE WAS
HOSPITALIZED
POST-OPERATIVELY FROM
2/1/21—2/3/21. HER
POST-OPERATIVE COURSE WAS
COMPLICATED BY ANEMIA
(HEMOGLOBIN DROPPED TO

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

8MG/DL RANGE) BUT SHE DID NOT REQUIRE TRANSFUSION. SHE REMAINED IN HOSPITAL FOR OBSERVATION AN EXTRA NIGHT FOR MONITORING OF ANEMIA. SHE WAS DISCHARGED ON PRN OXYCODONE (DOSE UNKNOWN) WHICH SHE TOOK FOR THE FIRST WEEK AND PRN TYLENOL 1000MG WHICH SHE STILL TAKES ON OCCASION BUT REPORTS TO BE RECOVERING NICELY AND IS ABOUT 80% BACK TO BASELINE. SHE WILL CONTINUE TO FOLLOW WITH HER ORTHOPEDIC SURGEON, NEXT FOLLOW-UP SCHEDULED 3/16/21.THIS IS AN SAE OF END STAGE OSTEOARTHRITIS WITH AVASCULAR NECROSIS OF THE RIGHT HIP JOINT REQUIRING HOSPITALIZATION FOR TOTAL HIP REPLACEMENT, NOT RELATED TO IP. THIS IS ALSO AND SAE OF PROLONGED HOSPITALIZATION RELATED TO POST-OPERATIVE ANEMIA, NOT RELATED TO IP. MEDICAL RECORDS ARE BEING REQUESTED.FOLLOW UP 24FEB2021: SENT VIA EMAIL TO SAFETY TEAM AS NOT ENOUGH CHARACTERS TO

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

COMPLETE IN EDC FIELD.	
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

AEID

Adverse event

POST OPERATIVE PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

01 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

07 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

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 <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

AEID

Adverse event

EXACERBATION OF
HYPERTENSION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

11 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

03 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

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 <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 06 Apr 2021 02:32:57

Generated On: 09 Jun 2021 17:02:25

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 15:59:27

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Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	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 (2)

Data signed: (b) (4) 09 Apr 2021 15:59:27

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Name of Medication ALENDRONATE

Prophylaxis Yes ☐
No ☒

Indication OSTEOPOROSIS

Dose per administration 35

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 15:59:27

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 15:59:27

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Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

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 (3)

Data signed: (b) (4) 09 Apr 2021 15:59:27

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 15:59:27

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Name of Medication CALCIUM

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 15:59:27

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	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 (5)

Data signed: (b) (4) 09 Apr 2021 15:59:27

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Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 15:59:27

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 15:59:27

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Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS LEFT KNEE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 15:59:27

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 15:59:27

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Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS LEFT KNEE

Dose per administration 440

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 15:59:27

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 15:59:27

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Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 15:59:27

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 15:59:27

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Name of Medication SEASONAL INFLUENZA
VACCINE

Prophylaxis Yes ☒
No ☐

Indication SEASONAL INFLUENZA
VACCINE

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	16 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 15:59:27

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 15:59:27

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Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication POST-OP PAIN (RIGHT HIP REPLACEMENT)

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 15:59:27

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	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)		03 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)		10 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication DEEP VEIN THROMBOSIS
PROPHYLAXIS

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

	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)	04 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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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US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

	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 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)	03 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
RIGHT HIP

Dose per administration 7.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

	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)	02 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 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

Name of Medication SPINAL ANESTHESIA

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
RIGHT HIP

Dose per administration UNK

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

If dose unit is Other, specify UNK

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRATHECAL	
Start date (dd MMM yyyy)	01 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)	01 FEB 2021	
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"/>

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

Name of Medication INTRAVENOUS FLUIDS
(UNKNOWN)

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
RIGHT HIP

Dose per administration UNK

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 (17)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input checked="" type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 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)		02 FEB 2021
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"/>

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

Name of Medication LOVENOX

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
RIGHT HIP

Dose per administration UNK

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 (18)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 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)		02 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
RIGHT HIP

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

	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)	02 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)		07 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

Name of Medication ANCEF (CEFAZOLIN)

Prophylaxis Yes ☒
No ☐

Indication PERIOPERATIVE PROPHYLAXIS

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 (20)

Data signed: (b) (4) 09 Apr 2021 15:59:27

Generated On: 09 Jun 2021 17:02:25

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

US3312434

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 21:58:59

Generated On: 09 Jun 2021 17:02:25

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3312434

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 06 Apr 2021 02:32:57

Generated On: 09 Jun 2021 17:02:25

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
01 FEB 2021	RIGHT HIP REPLACEMENT	Adverse Event	

US3312434

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:02:25

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

US3312434

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:02:25

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 ☐

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

SAEID	USA-US300-2021-MRNA-1273-P301000017
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

SAEID	USA-US300-2021-MRNA-1273-P301000017
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	22/FEB/2021 10:10
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

SAEID	USA-US300-2021-MRNA-1273-P301000017
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	25/FEB/2021 09:25
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

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form (3)

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

SAEID	USA-US300-2021-MRNA-1273-P301000017
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/MAR/2021 09:39
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

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form (4)

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

SAEID	USA-US300-2021-MRNA-1273-P301000017
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	18/MAR/2021 07:55
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

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form (5)

Data signed: (b) (4) 06 Apr 2021 02:32:58

Generated On: 09 Jun 2021 17:02:25

SAEID	USA-US300-2021-MRNA-1273-P301000017
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	24/MAR/2021 13:34
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3312434 (Prod: Johnson County Clin-Trials)

US3312434

Form: Participant Creation

Generated On: 09 Jun 2021 17:02:25

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'US3312434'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	01 Sep 2020 17:20:03

US3312434

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User closed query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 12:47:47
Query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed.' answered with 'updated' (Site from DM).	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:21:58
User opened query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 20:19:49
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	01 Sep 2020 18:26:43

US3312434

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '01 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	01 Sep 2020 17:20:04

US3312434

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

[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 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	01 Sep 2020 18:26:43

US3312434

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered 'SCRN'	System	01 Sep 2020 18:26:43

US3312434

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:25

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered (b) (6) 1951'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	01 Sep 2020 17:20:05

US3312434

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:25

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '69'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:27:21

US3312434

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:25

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered 'YEARS'	System	02 Sep 2020 16:27:21

US3312434

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:25

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered '69'	System	01 Sep 2020 18:26:57

US3312434

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:25

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Female (F)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:27:21

US3312434

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:25

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:27:21

US3312434

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:25

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:27:21

US3312434

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:25

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:27:21

US3312434

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:25

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:27:21

US3312434

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:25

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:27:21

US3312434

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:25

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:27:21

US3312434

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:25

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:27:21

US3312434

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:25

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:27:21

US3312434

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:25

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:27:21

US3312434

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:25

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 16:27:21

US3312434

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:25

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '1 Sep 2020'	Christa Estrada (b) (4)	01 Sep 2020 18:26:57

US3312434

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered 'Sep 2020'	System	01 Sep 2020 18:26:57

US3312434

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered '2020'	System	01 Sep 2020 18:26:57

US3312434

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:25

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Amendment 3 (3)'	Christa Estrada (b) (4)	01 Sep 2020 18:26:57

US3312434

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	01 Sep 2020 18:26:57

US3312434

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:25

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) Christa Estrada (b) (4)	01 Sep 2020 18:26:57

US3312434

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:25

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) Christa Estrada (b) (4)	01 Sep 2020 18:26:57

US3312434

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:25

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	01 Sep 2020 18:26:57

US3312434

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:25

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	01 Sep 2020 17:20:04

US3312434

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:25

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered 'I'	System	01 Sep 2020 18:27:03

US3312434

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	Christa Estrada (b) (4)	01 Sep 2020 18:27:03

US3312434

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:02:25

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:23:58

US3312434

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knee - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 16:26:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 16:26:57
Data point term sent to Coder	System	24 Sep 2020 16:26:08
User entered 'osteoarthritis left knee'	Karol Moore (b) (4)	24 Sep 2020 16:25:15

US3312434

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'un UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:25:15

US3312434

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:25:15

US3312434

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:25:15

US3312434

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) Karol Moore (b) (4)	24 Sep 2020 16:25:15

US3312434

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:25:15

US3312434

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered 'Jan 2010'	System	24 Sep 2020 16:25:15

US3312434

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered '2010'	System	24 Sep 2020 16:25:15

US3312434

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered empty.	System	24 Sep 2020 16:25:15

US3312434

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered empty.	System	24 Sep 2020 16:25:15

US3312434

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
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)	24 Sep 2020 16:26:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 16:26:56
Data point term sent to Coder	System	24 Sep 2020 16:26:10
User entered 'hypertension'	Karol Moore (b) (4)	24 Sep 2020 16:25:31

US3312434

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'un UNK 2018'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:25:31

US3312434

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:25:31

US3312434

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:25:31

US3312434

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:25:31

US3312434

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:25:31

US3312434

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered 'Jan 2018'	System	24 Sep 2020 16:25:31

US3312434

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered '2018'	System	24 Sep 2020 16:25:31

US3312434

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered empty.	System	24 Sep 2020 16:25:31

US3312434

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered empty.	System	24 Sep 2020 16:25:31

US3312434

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 16:26:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 16:26:56
Data point term sent to Coder	System	24 Sep 2020 16:26:10
User entered 'osteoporosis'	Karol Moore (b) (4)	24 Sep 2020 16:25:45

US3312434

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'un UNK 2018'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:25:45

US3312434

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:25:45

US3312434

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:25:45

US3312434

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:25:45

US3312434

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:25:45

US3312434

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:25

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered 'Jan 2018'	System	24 Sep 2020 16:25:45

US3312434

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered '2018'	System	24 Sep 2020 16:25:45

US3312434

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered empty.	System	24 Sep 2020 16:25:45

US3312434

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered empty.	System	24 Sep 2020 16:25:45

US3312434

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
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)	24 Sep 2020 16:26:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 16:26:56
Data point term sent to Coder	System	24 Sep 2020 16:26:12
User entered 'post menopausal'	Karol Moore (b) (4)	24 Sep 2020 16:25:56

US3312434

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'un UNK 2000'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:25:56

US3312434

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:25:56

US3312434

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:25:56

US3312434

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:25:56

US3312434

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:25:56

US3312434

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered 'Jan 2000'	System	24 Sep 2020 16:25:56

US3312434

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered '2000'	System	24 Sep 2020 16:25:56

US3312434

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered empty.	System	24 Sep 2020 16:25:56

US3312434

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered empty.	System	24 Sep 2020 16:25:56

US3312434

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 21:06:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 21:06:50
Data point term sent to Coder	System	23 Mar 2021 21:05:51
User entered 'Osteoarthritis Right hip'	(b) (4), (b) (6)	23 Mar 2021 21:05:27

US3312434

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:05:27

US3312434

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:05:27

US3312434

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:05:27

US3312434

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:05:27

US3312434

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:05:27

US3312434

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered 'Jan 2019'	System	23 Mar 2021 21:05:27

US3312434

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered '2019'	System	23 Mar 2021 21:05:27

US3312434

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered empty.	System	23 Mar 2021 21:05:27

US3312434

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered empty.	System	23 Mar 2021 21:05:27

US3312434

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:26:24

US3312434

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '01 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:26:24

US3312434

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '12:06'	(b) (4)	24 Sep 2020 16:26:24
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered '01 Sep 2020 12:06'	System	24 Sep 2020 16:26:24

US3312434

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '67' in	(b) (4)	24 Sep 2020 16:26:24
DataPoint set to visible.	Karol Moore (b) (4)	01 Sep 2020 18:27:03
	(b) (4)	
	System	

US3312434

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '129' lb	(b) (4) Karol Moore (b) (4)	24 Sep 2020 16:26:24
DataPoint set to visible.	(b) (4) System	01 Sep 2020 18:27:03

US3312434

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered '20.24650'	System	24 Sep 2020 16:26:24
DataPoint set to visible.	System	01 Sep 2020 18:27:03

US3312434

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered 'kg/m2'	System	24 Sep 2020 16:26:24
DataPoint set to visible.	System	01 Sep 2020 18:27:03

US3312434

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:26:24

US3312434

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:26:24

US3312434

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:26:24

US3312434

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:26:24

US3312434

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered 'bpm'	System	24 Sep 2020 16:26:24

US3312434

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	24 Sep 2020 16:26:24

US3312434

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered 'breaths/min'	System	24 Sep 2020 16:26:24

US3312434

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:26:24

US3312434

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered 'mmHg'	System	24 Sep 2020 16:26:24

US3312434

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	24 Sep 2020 16:26:24

US3312434

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User entered 'mmHg'	System	24 Sep 2020 16:26:24

US3312434

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48

US3312434

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48

US3312434

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:26:40

US3312434

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:25

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '01 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:26:40

US3312434

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '01 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:26:59

US3312434

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:26:59

US3312434

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Karol Moore (b) (4)	24 Sep 2020 16:26:59

US3312434

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:25

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:26:59

US3312434

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:26:59

US3312434

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:25

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:26:59

US3312434

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'un UNK 2000'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:26:59

US3312434

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:25

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:26:59

US3312434

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:25

[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 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:27:29

US3312434

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:25

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 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:27:29

US3312434

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:25

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 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:27:29

US3312434

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:25

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 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:27:29

US3312434

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:25

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 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:27:29

US3312434

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:25

[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 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:27:29

US3312434

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:25

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 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:27:29

US3312434

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:25

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 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:27:29

US3312434

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:25

[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 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:27:29

US3312434

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:25

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 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:27:29

US3312434

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:25

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 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:27:29

US3312434

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:25

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:27:29

US3312434

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:25

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:27:29

US3312434

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:25

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:27:29

US3312434

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:27:29

US3312434

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:25

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 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '0'	Karol Moore (b) (4)	24 Sep 2020 16:27:29

US3312434

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:25

[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 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:27:29

US3312434

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:25

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 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:27:29

US3312434

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:27:29

US3312434

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:25

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:27:29

US3312434

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:25

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:26:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'resides in community with ongoing person to person transmission'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:27:29

US3312434

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	01 Sep 2020 18:27:12

US3312434

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '1 Sep 2020'	(b) (4) Christa Estrada (b) (4)	01 Sep 2020 18:27:12

US3312434

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	01 Sep 2020 18:27:12

US3312434

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User entered 'VISIT1'	System	01 Sep 2020 18:27:12

US3312434

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '01 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	01 Sep 2020 18:04:38

US3312434

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:25

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '189425'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	01 Sep 2020 18:04:38

US3312434

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	01 Sep 2020 18:04:38

US3312434

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	Christa Estrada (b) (4)	01 Sep 2020 18:27:22

US3312434

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	Christa Estrada (b) (4)	01 Sep 2020 18:27:22

US3312434

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	01 Sep 2020 18:27:22

US3312434

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:25

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	01 Sep 2020 18:27:22

US3312434

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:25

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	01 Sep 2020 18:27:22

US3312434

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	24 Sep 2020 16:27:37
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 08:58:30
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:58:29

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:25

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:25

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4)	24 Sep 2020 16:28:17
	(b) (4)	

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '01 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '12:06'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User entered '01 Sep 2020 12:06'	System	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '97.9' F	(b) (4)	24 Sep 2020 16:28:17
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '65'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User entered 'bpm'	System	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '16'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User entered 'breaths/min'	System	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '139'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User entered 'mmHg'	System	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '81'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User entered 'mmHg'	System	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:25

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '01 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '13:55'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User entered '01 Sep 2020 13:55'	System	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '98.5' F	(b) (4)	24 Sep 2020 16:28:17
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '57'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User entered 'bpm'	System	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '12'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User entered 'breaths/min'	System	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '155'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User entered 'mmHg'	System	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '85'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User entered 'mmHg'	System	24 Sep 2020 16:28:17

US3312434

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:22

US3312434

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4)	24 Sep 2020 16:28:22
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	01 Sep 2020 18:27:49

US3312434

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) Christa Estrada (b) (4)	01 Sep 2020 18:27:49

US3312434

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	Christa Estrada (b) (4)	01 Sep 2020 18:27:49

US3312434

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 18:27:49

US3312434

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '1 Sep 2020'	Christa Estrada (b) (4)	01 Sep 2020 18:27:49

US3312434

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '13:24'	(b) (4) Christa Estrada (b) (4)	01 Sep 2020 18:27:49

US3312434

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User entered '1 Sep 2020 13:24'	System	01 Sep 2020 18:27:49

US3312434

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4)	01 Sep 2020 18:27:49

US3312434

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User entered 'ONCE'	System	01 Sep 2020 18:27:49

US3312434

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 18:27:49

US3312434

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:33

US3312434

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '01 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:33

US3312434

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '12:46'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:33

US3312434

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User entered '01 Sep 2020 12:46'	System	24 Sep 2020 16:28:33

US3312434

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:02:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '01 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:43

US3312434

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:43

US3312434

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:43

US3312434

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '12:38'	(b) (4)	24 Sep 2020 16:28:43
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User entered '01 Sep 2020 12:38'	System	24 Sep 2020 16:28:43

US3312434

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:43

US3312434

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:43

US3312434

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:43

US3312434

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:25

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User entered empty.	System	24 Sep 2020 16:28:43

US3312434

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:28:45

US3312434

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User entered '1'	System	24 Sep 2020 16:28:45

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T14:03:37', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'a39c550b-2662-4cd1-9d78-e0410c6c0466'	System	01 Sep 2020 19:04:31
User entered 'Yes (Y)'	System	01 Sep 2020 19:04:31

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T14:03:48', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'a39c550b-2662-4cd1-9d78-e0410c6c0466'	System	01 Sep 2020 19:04:31
User entered '98.5'	System	01 Sep 2020 19:04:31

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T14:04:13', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'a39c550b-2662-4cd1-9d78-e0410c6c0466'	System	01 Sep 2020 19:04:31
User entered 'No (N)'	System	01 Sep 2020 19:04:31

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T14:04:25', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'a39c550b-2662-4cd1-9d78-e0410c6c0466'	System	01 Sep 2020 19:04:31
User entered '01 Sep 2020 14:04'	System	01 Sep 2020 19:04:31

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '01 Sep 2020 13:44'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '01 Sep 2020 16:14'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T17:17:18', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '181a24de-cec0-45bb-ab2e-0c7ef24825c1'	System	01 Sep 2020 22:17:55
User entered 'Yes (Y)'	System	01 Sep 2020 22:17:55

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T17:17:27', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '181a24de-cec0-45bb-ab2e-0c7ef24825c1'	System	01 Sep 2020 22:17:55
User entered '97.9'	System	01 Sep 2020 22:17:55

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T17:17:32', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '181a24de-cec0-45bb-ab2e-0c7ef24825c1'	System	01 Sep 2020 22:17:55
User entered 'No (N)'	System	01 Sep 2020 22:17:55

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T17:17:51', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '181a24de-cec0-45bb-ab2e-0c7ef24825c1'	System	01 Sep 2020 22:17:55
User entered '01 Sep 2020 17:17'	System	01 Sep 2020 22:17:55

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '01 Sep 2020 17:09'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 2'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-02T17:44:11', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8ff0520b-d8a2-4ab8-9163-241fbf5292c7'	System	02 Sep 2020 22:44:36
User entered 'Yes (Y)'	System	02 Sep 2020 22:44:36

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-02T17:44:17', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8ff0520b-d8a2-4ab8-9163-241fbf5292c7'	System	02 Sep 2020 22:44:36
User entered '97.6'	System	02 Sep 2020 22:44:36

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-02T17:44:22', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8ff0520b-d8a2-4ab8-9163-241fbf5292c7'	System	02 Sep 2020 22:44:36
User entered 'No (N)'	System	02 Sep 2020 22:44:36

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-02T17:44:30', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8ff0520b-d8a2-4ab8-9163-241fbf5292c7'	System	02 Sep 2020 22:44:36
User entered '02 Sep 2020 17:44'	System	02 Sep 2020 22:44:36

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 3'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-03T15:24:14', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'f393b7e0-07d2-4716-9ee0-3cff24506c93'	System	03 Sep 2020 20:24:35
User entered 'Yes (Y)'	System	03 Sep 2020 20:24:35

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-03T15:24:21', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'f393b7e0-07d2-4716-9ee0-3cff24506c93'	System	03 Sep 2020 20:24:35
User entered '97.6'	System	03 Sep 2020 20:24:35

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-03T15:24:25', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'f393b7e0-07d2-4716-9ee0-3cff24506c93'	System	03 Sep 2020 20:24:35
User entered 'No (N)'	System	03 Sep 2020 20:24:35

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-03T15:24:31', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'f393b7e0-07d2-4716-9ee0-3cff24506c93'	System	03 Sep 2020 20:24:35
User entered '03 Sep 2020 15:24'	System	03 Sep 2020 20:24:35

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 4'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-04T15:52:11', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'dd54a927-ef4b-4a6b-b236-84c6d581731a'	System	04 Sep 2020 20:52:30
User entered 'Yes (Y)'	System	04 Sep 2020 20:52:30

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-04T15:52:17', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'dd54a927-ef4b-4a6b-b236-84c6d581731a'	System	04 Sep 2020 20:52:30
User entered '97.2'	System	04 Sep 2020 20:52:30

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-04T15:52:21', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'dd54a927-ef4b-4a6b-b236-84c6d581731a'	System	04 Sep 2020 20:52:30
User entered 'No (N)'	System	04 Sep 2020 20:52:30

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-04T15:52:27', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'dd54a927-ef4b-4a6b-b236-84c6d581731a'	System	04 Sep 2020 20:52:30
User entered '04 Sep 2020 15:52'	System	04 Sep 2020 20:52:30

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 5'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-05T20:49:36', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '513a8457-1984-407b-8571-fbe69176905c'	System	06 Sep 2020 01:49:55
User entered 'Yes (Y)'	System	06 Sep 2020 01:49:55

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-05T20:49:43', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '513a8457-1984-407b-8571-fbe69176905c' User entered '97.4'	System	06 Sep 2020 01:49:55
	System	06 Sep 2020 01:49:55

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-05T20:49:46', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '513a8457-1984-407b-8571-fbe69176905c'	System	06 Sep 2020 01:49:55
User entered 'No (N)'	System	06 Sep 2020 01:49:55

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-05T20:49:53', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '513a8457-1984-407b-8571-fbe69176905c'	System	06 Sep 2020 01:49:55
User entered '05 Sep 2020 20:49'	System	06 Sep 2020 01:49:55

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 6'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-06T14:36:58', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '4719a07c-0e7f-41f8-a3f2-d53e4b3d2dcd'	System	06 Sep 2020 19:37:18
User entered 'Yes (Y)'	System	06 Sep 2020 19:37:18

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-06T14:37:04', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '4719a07c-0e7f-41f8-a3f2-d53e4b3d2dcd'	System	06 Sep 2020 19:37:18
User entered '97.7'	System	06 Sep 2020 19:37:18

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-06T14:37:07', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '4719a07c-0e7f-41f8-a3f2-d53e4b3d2dcd'	System	06 Sep 2020 19:37:18
User entered 'No (N)'	System	06 Sep 2020 19:37:18

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-06T14:37:13', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '4719a07c-0e7f-41f8-a3f2-d53e4b3d2dcd'	System	06 Sep 2020 19:37:18
User entered '06 Sep 2020 14:37'	System	06 Sep 2020 19:37:18

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 7'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-07T17:58:14', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '1f42ceec-9159-472a-8299-5b06716fed16'	System	07 Sep 2020 22:58:38
User entered 'Yes (Y)'	System	07 Sep 2020 22:58:38

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-07T17:58:27', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '1f42ceec-9159-472a-8299-5b06716fed16'	System	07 Sep 2020 22:58:38
User entered '97.7'	System	07 Sep 2020 22:58:38

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-07T17:58:30', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '1f42ceec-9159-472a-8299-5b06716fed16'	System	07 Sep 2020 22:58:38
User entered 'No (N)'	System	07 Sep 2020 22:58:38

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-07T17:58:35', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '1f42ceec-9159-472a-8299-5b06716fed16'	System	07 Sep 2020 22:58:38
User entered '07 Sep 2020 17:58'	System	07 Sep 2020 22:58:38

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T14:05:13', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '18392c19-ca8e-4b29-bd5a-a7763753c7ff'	System	01 Sep 2020 19:05:50
User entered 'None (1)'	System	01 Sep 2020 19:05:50

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T14:05:34', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '18392c19-ca8e-4b29-bd5a-a7763753c7ff'	System	01 Sep 2020 19:05:50
User entered 'No (N)'	System	01 Sep 2020 19:05:50

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T14:05:38', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '18392c19-ca8e-4b29-bd5a-a7763753c7ff'	System	01 Sep 2020 19:05:50
User entered 'No (N)'	System	01 Sep 2020 19:05:50

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T14:05:42', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '18392c19-ca8e-4b29-bd5a-a7763753c7ff'	System	01 Sep 2020 19:05:50
User entered 'None (1)'	System	01 Sep 2020 19:05:50

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T14:05:47', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '18392c19-ca8e-4b29-bd5a-a7763753c7ff'	System	01 Sep 2020 19:05:50
User entered '01 Sep 2020 14:05'	System	01 Sep 2020 19:05:50

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '01 Sep 2020 13:44'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '01 Sep 2020 16:14'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T17:18:03', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'e4b944a4-bc6f-49bb-9498-26226c627ec2'	System	01 Sep 2020 22:18:32
User entered 'None (1)'	System	01 Sep 2020 22:18:32

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T17:18:11', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'e4b944a4-bc6f-49bb-9498-26226c627ec2'	System	01 Sep 2020 22:18:32
User entered 'No (N)'	System	01 Sep 2020 22:18:32

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T17:18:15', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'e4b944a4-bc6f-49bb-9498-26226c627ec2'	System	01 Sep 2020 22:18:32
User entered 'No (N)'	System	01 Sep 2020 22:18:32

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T17:18:21', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'e4b944a4-bc6f-49bb-9498-26226c627ec2'	System	01 Sep 2020 22:18:32
User entered 'None (1)'	System	01 Sep 2020 22:18:32

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T17:18:28', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'e4b944a4-bc6f-49bb-9498-26226c627ec2'	System	01 Sep 2020 22:18:32
User entered '01 Sep 2020 17:18'	System	01 Sep 2020 22:18:32

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '01 Sep 2020 17:09'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 2'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-02T17:44:38', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '438d87ca-0221-4fbe-bceb-f2a7e824f473'	System	02 Sep 2020 22:44:59
User entered 'None (1)'	System	02 Sep 2020 22:44:59

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-02T17:44:42', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '438d87ca-0221-4fbe-bceb-f2a7e824f473'	System	02 Sep 2020 22:44:59
User entered 'No (N)'	System	02 Sep 2020 22:44:59

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-02T17:44:45', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '438d87ca-0221-4fbe-bceb-f2a7e824f473'	System	02 Sep 2020 22:44:59
User entered 'No (N)'	System	02 Sep 2020 22:44:59

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-02T17:44:49', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '438d87ca-0221-4fbe-bceb-f2a7e824f473'	System	02 Sep 2020 22:44:59
User entered 'None (1)'	System	02 Sep 2020 22:44:59

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-02T17:44:56', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '438d87ca-0221-4fbe-bceb-f2a7e824f473'	System	02 Sep 2020 22:44:59
User entered '02 Sep 2020 17:44'	System	02 Sep 2020 22:44:59

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 3'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-03T15:24:39', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '40fb541b-8f49-4b3d-af45-8d1555a60302'	System	03 Sep 2020 20:25:06
User entered 'None (1)'	System	03 Sep 2020 20:25:06

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-03T15:24:42', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '40fb541b-8f49-4b3d-af45-8d1555a60302'	System	03 Sep 2020 20:25:06
User entered 'No (N)'	System	03 Sep 2020 20:25:06

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-03T15:24:45', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '40fb541b-8f49-4b3d-af45-8d1555a60302'	System	03 Sep 2020 20:25:06
User entered 'No (N)'	System	03 Sep 2020 20:25:06

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-03T15:24:49', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '40fb541b-8f49-4b3d-af45-8d1555a60302'	System	03 Sep 2020 20:25:06
User entered 'None (1)'	System	03 Sep 2020 20:25:06

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-03T15:25:01', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '40fb541b-8f49-4b3d-af45-8d1555a60302'	System	03 Sep 2020 20:25:06
User entered '03 Sep 2020 15:25'	System	03 Sep 2020 20:25:06

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 4'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-04T15:52:32', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '20debcd2-f918-4f4c-bb33-cc9a3a819908'	System	04 Sep 2020 20:52:54
User entered 'None (1)'	System	04 Sep 2020 20:52:54

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-04T15:52:35', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '20debcd2-f918-4f4c-bb33-cc9a3a819908'	System	04 Sep 2020 20:52:54
User entered 'No (N)'	System	04 Sep 2020 20:52:54

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-04T15:52:39', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '20debcd2-f918-4f4c-bb33-cc9a3a819908'	System	04 Sep 2020 20:52:54
User entered 'No (N)'	System	04 Sep 2020 20:52:54

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-04T15:52:44', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '20debcd2-f918-4f4c-bb33-cc9a3a819908'	System	04 Sep 2020 20:52:54
User entered 'None (1)'	System	04 Sep 2020 20:52:54

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-04T15:52:50', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '20debcd2-f918-4f4c-bb33-cc9a3a819908'	System	04 Sep 2020 20:52:54
User entered '04 Sep 2020 15:52'	System	04 Sep 2020 20:52:54

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 5'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-05T20:49:59', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'f5bb4853-a9a0-4b4d-a725-1e10596dc06d'	System	06 Sep 2020 01:50:24
User entered 'None (1)'	System	06 Sep 2020 01:50:24

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-05T20:50:02', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'f5bb4853-a9a0-4b4d-a725-1e10596dc06d'	System	06 Sep 2020 01:50:24
User entered 'No (N)'	System	06 Sep 2020 01:50:24

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-05T20:50:05', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'f5bb4853-a9a0-4b4d-a725-1e10596dc06d'	System	06 Sep 2020 01:50:24
User entered 'No (N)'	System	06 Sep 2020 01:50:24

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-05T20:50:11', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'f5bb4853-a9a0-4b4d-a725-1e10596dc06d'	System	06 Sep 2020 01:50:24
User entered 'None (1)'	System	06 Sep 2020 01:50:24

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-05T20:50:16', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'f5bb4853-a9a0-4b4d-a725-1e10596dc06d'	System	06 Sep 2020 01:50:24
User entered '05 Sep 2020 20:50'	System	06 Sep 2020 01:50:24

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 6'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-06T14:37:18', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '748ecd6e-93d3-479b-8db8-262e912b4738'	System	06 Sep 2020 19:37:38
User entered 'None (1)'	System	06 Sep 2020 19:37:38

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-06T14:37:21', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '748ecd6e-93d3-479b-8db8-262e912b4738'	System	06 Sep 2020 19:37:38
User entered 'No (N)'	System	06 Sep 2020 19:37:38

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-06T14:37:25', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '748ecd6e-93d3-479b-8db8-262e912b4738'	System	06 Sep 2020 19:37:38
User entered 'No (N)'	System	06 Sep 2020 19:37:38

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-06T14:37:29', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '748ecd6e-93d3-479b-8db8-262e912b4738'	System	06 Sep 2020 19:37:38
User entered 'None (1)'	System	06 Sep 2020 19:37:38

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-06T14:37:34', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '748ecd6e-93d3-479b-8db8-262e912b4738'	System	06 Sep 2020 19:37:38
User entered '06 Sep 2020 14:37'	System	06 Sep 2020 19:37:38

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 7'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-07T17:58:40', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'f4746b43-5fad-41c4-bb0e-0756f10cb87a'	System	07 Sep 2020 22:59:00
User entered 'None (1)'	System	07 Sep 2020 22:59:00

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-07T17:58:44', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'f4746b43-5fad-41c4-bb0e-0756f10cb87a'	System	07 Sep 2020 22:59:00
User entered 'No (N)'	System	07 Sep 2020 22:59:00

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-07T17:58:46', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'f4746b43-5fad-41c4-bb0e-0756f10cb87a'	System	07 Sep 2020 22:59:00
User entered 'No (N)'	System	07 Sep 2020 22:59:00

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-07T17:58:51', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'f4746b43-5fad-41c4-bb0e-0756f10cb87a'	System	07 Sep 2020 22:59:00
User entered 'None (1)'	System	07 Sep 2020 22:59:00

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-07T17:58:57', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'f4746b43-5fad-41c4-bb0e-0756f10cb87a'	System	07 Sep 2020 22:59:00
User entered '07 Sep 2020 17:58'	System	07 Sep 2020 22:59:00

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T14:06:27', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '561526f2-db37-4aa4-bf81-4effb586e720'	System	01 Sep 2020 19:07:04
User entered 'None (0)'	System	01 Sep 2020 19:07:04

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T14:06:38', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '561526f2-db37-4aa4-bf81-4effb586e720'	System	01 Sep 2020 19:07:04
User entered 'None (0)'	System	01 Sep 2020 19:07:04

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T14:06:41', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '561526f2-db37-4aa4-bf81-4effb586e720'	System	01 Sep 2020 19:07:04
User entered 'None (0)'	System	01 Sep 2020 19:07:04

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T14:06:43', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '561526f2-db37-4aa4-bf81-4effb586e720'	System	01 Sep 2020 19:07:04
User entered 'None (0)'	System	01 Sep 2020 19:07:04

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T14:06:46', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '561526f2-db37-4aa4-bf81-4effb586e720'	System	01 Sep 2020 19:07:04
User entered 'None (0)'	System	01 Sep 2020 19:07:04

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T14:06:49', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '561526f2-db37-4aa4-bf81-4effb586e720'	System	01 Sep 2020 19:07:04
User entered 'None (0)'	System	01 Sep 2020 19:07:04

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T14:06:53', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '561526f2-db37-4aa4-bf81-4effb586e720'	System	01 Sep 2020 19:07:04
User entered 'No (N)'	System	01 Sep 2020 19:07:04

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T14:06:57', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '561526f2-db37-4aa4-bf81-4effb586e720'	System	01 Sep 2020 19:07:04
User entered '01 Sep 2020 14:06'	System	01 Sep 2020 19:07:04

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '01 Sep 2020 13:44'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '01 Sep 2020 16:14'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T17:18:35', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8cf89586-2ea3-4d5b-abd7-d4c80901f176'	System	01 Sep 2020 22:19:11
User entered 'None (0)'	System	01 Sep 2020 22:19:11

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T17:18:39', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8cf89586-2ea3-4d5b-abd7-d4c80901f176'	System	01 Sep 2020 22:19:11
User entered 'None (0)'	System	01 Sep 2020 22:19:11

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T17:18:42', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8cf89586-2ea3-4d5b-abd7-d4c80901f176'	System	01 Sep 2020 22:19:11
User entered 'None (0)'	System	01 Sep 2020 22:19:11

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T17:18:46', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8cf89586-2ea3-4d5b-abd7-d4c80901f176'	System	01 Sep 2020 22:19:11
User entered 'None (0)'	System	01 Sep 2020 22:19:11

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T17:18:48', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8cf89586-2ea3-4d5b-abd7-d4c80901f176'	System	01 Sep 2020 22:19:11
User entered 'None (0)'	System	01 Sep 2020 22:19:11

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T17:18:53', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8cf89586-2ea3-4d5b-abd7-d4c80901f176'	System	01 Sep 2020 22:19:11
User entered 'None (0)'	System	01 Sep 2020 22:19:11

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T17:18:59', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8cf89586-2ea3-4d5b-abd7-d4c80901f176'	System	01 Sep 2020 22:19:11
User entered 'No (N)'	System	01 Sep 2020 22:19:11

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-01T17:19:05', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8cf89586-2ea3-4d5b-abd7-d4c80901f176'	System	01 Sep 2020 22:19:11
User entered '01 Sep 2020 17:19'	System	01 Sep 2020 22:19:11

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '01 Sep 2020 17:09'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 2'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-02T17:45:01', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '399d9692-9824-41c1-88ec-279fa5564f1f'	System	02 Sep 2020 22:45:31
User entered 'None (0)'	System	02 Sep 2020 22:45:31

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-02T17:45:03', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '399d9692-9824-41c1-88ec-279fa5564f1f'	System	02 Sep 2020 22:45:31
User entered 'None (0)'	System	02 Sep 2020 22:45:31

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-02T17:45:06', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '399d9692-9824-41c1-88ec-279fa5564f1f'	System	02 Sep 2020 22:45:31
User entered 'None (0)'	System	02 Sep 2020 22:45:31

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-02T17:45:08', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '399d9692-9824-41c1-88ec-279fa5564f1f'	System	02 Sep 2020 22:45:31
User entered 'None (0)'	System	02 Sep 2020 22:45:31

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-02T17:45:11', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '399d9692-9824-41c1-88ec-279fa5564f1f'	System	02 Sep 2020 22:45:31
User entered 'None (0)'	System	02 Sep 2020 22:45:31

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-02T17:45:13', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '399d9692-9824-41c1-88ec-279fa5564f1f'	System	02 Sep 2020 22:45:31
User entered 'None (0)'	System	02 Sep 2020 22:45:31

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-02T17:45:16', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '399d9692-9824-41c1-88ec-279fa5564f1f'	System	02 Sep 2020 22:45:31
User entered 'No (N)'	System	02 Sep 2020 22:45:31

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-02T17:45:27', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '399d9692-9824-41c1-88ec-279fa5564f1f'	System	02 Sep 2020 22:45:31
User entered '02 Sep 2020 17:45'	System	02 Sep 2020 22:45:31

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 3'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-03T15:25:06', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c54d2272-6652-4fda-8b5a-30d7847cbebb'	System	03 Sep 2020 20:25:36
User entered 'None (0)'	System	03 Sep 2020 20:25:36

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-03T15:25:13', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c54d2272-6652-4fda-8b5a-30d7847cbebb'	System	03 Sep 2020 20:25:36
User entered 'None (0)'	System	03 Sep 2020 20:25:36

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-03T15:25:15', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c54d2272-6652-4fda-8b5a-30d7847cbebb'	System	03 Sep 2020 20:25:36
User entered 'None (0)'	System	03 Sep 2020 20:25:36

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-03T15:25:18', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c54d2272-6652-4fda-8b5a-30d7847cbebb'	System	03 Sep 2020 20:25:36
User entered 'None (0)'	System	03 Sep 2020 20:25:36

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-03T15:25:20', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c54d2272-6652-4fda-8b5a-30d7847cbebb'	System	03 Sep 2020 20:25:36
User entered 'None (0)'	System	03 Sep 2020 20:25:36

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-03T15:25:22', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c54d2272-6652-4fda-8b5a-30d7847cbebb'	System	03 Sep 2020 20:25:36
User entered 'None (0)'	System	03 Sep 2020 20:25:36

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-03T15:25:25', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c54d2272-6652-4fda-8b5a-30d7847cbebb'	System	03 Sep 2020 20:25:36
User entered 'No (N)'	System	03 Sep 2020 20:25:36

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-03T15:25:33', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c54d2272-6652-4fda-8b5a-30d7847cbebb'	System	03 Sep 2020 20:25:36
User entered '03 Sep 2020 15:25'	System	03 Sep 2020 20:25:36

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 4'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-04T15:52:56', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'a34ce9dc-9cdc-46e5-bbdc-14e09d5ca9f2'	System	04 Sep 2020 20:53:28
User entered 'None (0)'	System	04 Sep 2020 20:53:28

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-04T15:53:03', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'a34ce9dc-9cdc-46e5-bbdc-14e09d5ca9f2'	System	04 Sep 2020 20:53:28
User entered 'None (0)'	System	04 Sep 2020 20:53:28

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-04T15:53:07', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'a34ce9dc-9cdc-46e5-bbdc-14e09d5ca9f2'	System	04 Sep 2020 20:53:28
User entered 'None (0)'	System	04 Sep 2020 20:53:28

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-04T15:53:09', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'a34ce9dc-9cdc-46e5-bbdc-14e09d5ca9f2'	System	04 Sep 2020 20:53:28
User entered 'None (0)'	System	04 Sep 2020 20:53:28

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-04T15:53:12', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'a34ce9dc-9cdc-46e5-bbdc-14e09d5ca9f2'	System	04 Sep 2020 20:53:28
User entered 'None (0)'	System	04 Sep 2020 20:53:28

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-04T15:53:14', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'a34ce9dc-9cdc-46e5-bbdc-14e09d5ca9f2'	System	04 Sep 2020 20:53:28
User entered 'None (0)'	System	04 Sep 2020 20:53:28

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-04T15:53:17', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'a34ce9dc-9cdc-46e5-bbdc-14e09d5ca9f2'	System	04 Sep 2020 20:53:28
User entered 'No (N)'	System	04 Sep 2020 20:53:28

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-04T15:53:23', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'a34ce9dc-9cdc-46e5-bbdc-14e09d5ca9f2'	System	04 Sep 2020 20:53:28
User entered '04 Sep 2020 15:53'	System	04 Sep 2020 20:53:28

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 5'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-05T20:50:21', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c4455949-a00f-41a8-a065-19d5a7ffb907'	System	06 Sep 2020 01:50:47
User entered 'None (0)'	System	06 Sep 2020 01:50:47

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-05T20:50:24', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c4455949-a00f-41a8-a065-19d5a7ffb907'	System	06 Sep 2020 01:50:47
User entered 'None (0)'	System	06 Sep 2020 01:50:47

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-05T20:50:26', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c4455949-a00f-41a8-a065-19d5a7ffb907'	System	06 Sep 2020 01:50:47
User entered 'None (0)'	System	06 Sep 2020 01:50:47

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-05T20:50:28', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c4455949-a00f-41a8-a065-19d5a7ffb907'	System	06 Sep 2020 01:50:47
User entered 'None (0)'	System	06 Sep 2020 01:50:47

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-05T20:50:30', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c4455949-a00f-41a8-a065-19d5a7ffb907'	System	06 Sep 2020 01:50:47
User entered 'None (0)'	System	06 Sep 2020 01:50:47

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-05T20:50:33', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c4455949-a00f-41a8-a065-19d5a7ffb907'	System	06 Sep 2020 01:50:47
User entered 'None (0)'	System	06 Sep 2020 01:50:47

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-05T20:50:36', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c4455949-a00f-41a8-a065-19d5a7ffb907'	System	06 Sep 2020 01:50:47
User entered 'No (N)'	System	06 Sep 2020 01:50:47

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-05T20:50:42', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c4455949-a00f-41a8-a065-19d5a7ffb907'	System	06 Sep 2020 01:50:47
User entered '05 Sep 2020 20:50'	System	06 Sep 2020 01:50:47

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 6'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-06T14:37:39', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '109c714e-467d-49bd-bdd6-38fd811a022b'	System	06 Sep 2020 19:38:00
User entered 'None (0)'	System	06 Sep 2020 19:38:00

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-06T14:37:41', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '109c714e-467d-49bd-bdd6-38fd811a022b'	System	06 Sep 2020 19:38:00
User entered 'None (0)'	System	06 Sep 2020 19:38:00

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-06T14:37:43', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '109c714e-467d-49bd-bdd6-38fd811a022b'	System	06 Sep 2020 19:38:00
User entered 'None (0)'	System	06 Sep 2020 19:38:00

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-06T14:37:45', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '109c714e-467d-49bd-bdd6-38fd811a022b'	System	06 Sep 2020 19:38:00
User entered 'None (0)'	System	06 Sep 2020 19:38:00

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-06T14:37:47', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '109c714e-467d-49bd-bdd6-38fd811a022b'	System	06 Sep 2020 19:38:00
User entered 'None (0)'	System	06 Sep 2020 19:38:00

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-06T14:37:49', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '109c714e-467d-49bd-bdd6-38fd811a022b'	System	06 Sep 2020 19:38:00
User entered 'None (0)'	System	06 Sep 2020 19:38:00

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-06T14:37:51', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '109c714e-467d-49bd-bdd6-38fd811a022b'	System	06 Sep 2020 19:38:00
User entered 'No (N)'	System	06 Sep 2020 19:38:00

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-06T14:37:57', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '109c714e-467d-49bd-bdd6-38fd811a022b'	System	06 Sep 2020 19:38:00
User entered '06 Sep 2020 14:37'	System	06 Sep 2020 19:38:00

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 7'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-07T17:59:02', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'dac5b46f-fd2e-4623-8f12-9f312115d1eb'	System	07 Sep 2020 22:59:29
User entered 'None (0)'	System	07 Sep 2020 22:59:29

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-07T17:59:05', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'dac5b46f-fd2e-4623-8f12-9f312115d1eb'	System	07 Sep 2020 22:59:29
User entered 'None (0)'	System	07 Sep 2020 22:59:29

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-07T17:59:07', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'dac5b46f-fd2e-4623-8f12-9f312115d1eb'	System	07 Sep 2020 22:59:29
User entered 'None (0)'	System	07 Sep 2020 22:59:29

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-07T17:59:09', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'dac5b46f-fd2e-4623-8f12-9f312115d1eb'	System	07 Sep 2020 22:59:29
User entered 'None (0)'	System	07 Sep 2020 22:59:29

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-07T17:59:14', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'dac5b46f-fd2e-4623-8f12-9f312115d1eb'	System	07 Sep 2020 22:59:29
User entered 'None (0)'	System	07 Sep 2020 22:59:29

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-07T17:59:16', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'dac5b46f-fd2e-4623-8f12-9f312115d1eb'	System	07 Sep 2020 22:59:29
User entered 'None (0)'	System	07 Sep 2020 22:59:29

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-07T17:59:19', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'dac5b46f-fd2e-4623-8f12-9f312115d1eb'	System	07 Sep 2020 22:59:29
User entered 'No (N)'	System	07 Sep 2020 22:59:29

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-07T17:59:26', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'dac5b46f-fd2e-4623-8f12-9f312115d1eb'	System	07 Sep 2020 22:59:29
User entered '07 Sep 2020 17:59'	System	07 Sep 2020 22:59:29

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 18:27:49

US3312434

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:29:37

US3312434

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '8 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:29:37

US3312434

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:29:37

US3312434

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4)	24 Sep 2020 16:29:37
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:29:59

US3312434

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User entered 'I'	System	24 Sep 2020 16:29:59

US3312434

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4)	24 Sep 2020 16:30:09
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '15 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:30:09

US3312434

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:30:09

US3312434

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4)	24 Sep 2020 16:30:09
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:30:14

US3312434

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:52:43
User entered 'I'	System	24 Sep 2020 16:30:14

US3312434

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:14
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4)	24 Sep 2020 16:30:48
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:14
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '22 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:30:48

US3312434

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:14
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:30:48

US3312434

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:14
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4)	24 Sep 2020 16:30:48
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:14
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4)	24 Sep 2020 16:30:51
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:14
User entered 'I'	System	24 Sep 2020 16:30:51

US3312434

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:09

US3312434

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:09

US3312434

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:09

US3312434

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered 'VISIT2'	System	29 Sep 2020 18:02:09

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '29 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '11:37'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered '29 Sep 2020 11:37'	System	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '98.3' F	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '61'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered 'bpm'	System	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '16'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered 'breaths/min'	System	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '168'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered 'mmHg'	System	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '89'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered 'mmHg'	System	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '29 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '13:26'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered '29 Sep 2020 13:26'	System	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '97.8' F	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '62'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered 'bpm'	System	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered 'breaths/min'	System	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '156'	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered 'mmHg'	System	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '89'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered 'mmHg'	System	17 Oct 2020 23:36:31

US3312434

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:38:07

US3312434

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '29 Sep 2020'	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:38:07

US3312434

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:32

US3312434

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:32

US3312434

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

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)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:32

US3312434

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 18:02:32

US3312434

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:32

US3312434

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '12:55'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:32

US3312434

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered '29 Sep 2020 12:55'	System	29 Sep 2020 18:02:32

US3312434

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:32

US3312434

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered 'ONCE'	System	29 Sep 2020 18:02:32

US3312434

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 18:02:32

US3312434

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:38:19

US3312434

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '29 Sep 2020'	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:38:19

US3312434

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '12:10'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:38:19

US3312434

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered '29 Sep 2020 12:10'	System	17 Oct 2020 23:38:19

US3312434

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:02:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '29 Sep 2020'	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:38:29

US3312434

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:38:29

US3312434

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:38:29

US3312434

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '11:58'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:38:29

US3312434

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered '29 Sep 2020 11:58'	System	17 Oct 2020 23:38:29

US3312434

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:38:29

US3312434

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:38:29

US3312434

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:38:29

US3312434

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:25

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered empty.	System	17 Oct 2020 23:38:29

US3312434

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:02:38

US3312434

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered 'I'	System	29 Sep 2020 18:02:38

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T13:28:45', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'efcc90cc-64ed-421b-b119-57fd33b17f2c'	System	29 Sep 2020 18:29:06
User entered 'Yes (Y)'	System	29 Sep 2020 18:29:06

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T13:28:51', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'efcc90cc-64ed-421b-b119-57fd33b17f2c'	System	29 Sep 2020 18:29:06
User entered '97.8'	System	29 Sep 2020 18:29:06

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T13:28:56', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'efcc90cc-64ed-421b-b119-57fd33b17f2c'	System	29 Sep 2020 18:29:06
User entered 'No (N)'	System	29 Sep 2020 18:29:06

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T13:29:01', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'efcc90cc-64ed-421b-b119-57fd33b17f2c'	System	29 Sep 2020 18:29:06
User entered '29 Sep 2020 13:29'	System	29 Sep 2020 18:29:06

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '29 Sep 2020 13:15'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '29 Sep 2020 15:45'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T18:20:53', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '76c294ee-d732-46bb-a7f7-2f4b325c73b3'	System	29 Sep 2020 23:21:14
User entered 'Yes (Y)'	System	29 Sep 2020 23:21:14

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T18:21:02', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '76c294ee-d732-46bb-a7f7-2f4b325c73b3'	System	29 Sep 2020 23:21:14
User entered '97.8'	System	29 Sep 2020 23:21:14

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T18:21:06', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '76c294ee-d732-46bb-a7f7-2f4b325c73b3'	System	29 Sep 2020 23:21:14
User entered 'No (N)'	System	29 Sep 2020 23:21:14

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T18:21:11', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '76c294ee-d732-46bb-a7f7-2f4b325c73b3'	System	29 Sep 2020 23:21:14
User entered '29 Sep 2020 18:21'	System	29 Sep 2020 23:21:14

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '29 Sep 2020 16:40'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 2'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-30T18:27:49', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '649d8832-75da-440c-9d5c-7720ef5c2410'	System	30 Sep 2020 23:28:05
User entered 'Yes (Y)'	System	30 Sep 2020 23:28:05

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-30T18:27:55', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '649d8832-75da-440c-9d5c-7720ef5c2410'	System	30 Sep 2020 23:28:05
User entered '98.4'	System	30 Sep 2020 23:28:05

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-30T18:27:58', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '649d8832-75da-440c-9d5c-7720ef5c2410'	System	30 Sep 2020 23:28:05
User entered 'No (N)'	System	30 Sep 2020 23:28:05

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-30T18:28:02', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '649d8832-75da-440c-9d5c-7720ef5c2410'	System	30 Sep 2020 23:28:05
User entered '30 Sep 2020 18:28'	System	30 Sep 2020 23:28:05

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 3'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-01T17:11:16', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '710b5589-b5de-4541-95aa-6ac4f3c23bee'	System	01 Oct 2020 22:11:41
User entered 'Yes (Y)'	System	01 Oct 2020 22:11:41

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-01T17:11:27', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '710b5589-b5de-4541-95aa-6ac4f3c23bee'	System	01 Oct 2020 22:11:41
User entered '97.8'	System	01 Oct 2020 22:11:41

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-01T17:11:31', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '710b5589-b5de-4541-95aa-6ac4f3c23bee'	System	01 Oct 2020 22:11:41
User entered 'No (N)'	System	01 Oct 2020 22:11:41

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-01T17:11:35', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '710b5589-b5de-4541-95aa-6ac4f3c23bee'	System	01 Oct 2020 22:11:41
User entered '01 Oct 2020 17:11'	System	01 Oct 2020 22:11:41

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 4'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-02T18:13:13', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '224f587c-c03f-42ff-8e3a-fe630a8103ab'	System	02 Oct 2020 23:13:29
User entered 'Yes (Y)'	System	02 Oct 2020 23:13:29

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-02T18:13:19', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '224f587c-c03f-42ff-8e3a-fe630a8103ab'	System	02 Oct 2020 23:13:29
User entered '97.6'	System	02 Oct 2020 23:13:29

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-02T18:13:22', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '224f587c-c03f-42ff-8e3a-fe630a8103ab'	System	02 Oct 2020 23:13:29
User entered 'No (N)'	System	02 Oct 2020 23:13:29

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-02T18:13:26', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '224f587c-c03f-42ff-8e3a-fe630a8103ab'	System	02 Oct 2020 23:13:29
User entered '02 Oct 2020 18:13'	System	02 Oct 2020 23:13:29

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 5'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-03T16:43:24', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8a6c7f47-86b9-4f69-a0b5-ccf459187f42'	System	03 Oct 2020 21:43:38
User entered 'Yes (Y)'	System	03 Oct 2020 21:43:38

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-03T16:43:29', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8a6c7f47-86b9-4f69-a0b5-ccf459187f42'	System	03 Oct 2020 21:43:38
User entered '97.6'	System	03 Oct 2020 21:43:38

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-03T16:43:32', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8a6c7f47-86b9-4f69-a0b5-ccf459187f42'	System	03 Oct 2020 21:43:38
User entered 'No (N)'	System	03 Oct 2020 21:43:38

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-03T16:43:36', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8a6c7f47-86b9-4f69-a0b5-ccf459187f42'	System	03 Oct 2020 21:43:38
User entered '03 Oct 2020 16:43'	System	03 Oct 2020 21:43:38

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 6'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-04T15:50:21', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '9aa36cec-185e-4087-886b-a8bf81e81a75'	System	04 Oct 2020 20:50:39
User entered 'Yes (Y)'	System	04 Oct 2020 20:50:39

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-04T15:50:29', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '9aa36cec-185e-4087-886b-a8bf81e81a75'	System	04 Oct 2020 20:50:39
User entered '97.5'	System	04 Oct 2020 20:50:39

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-04T15:50:32', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '9aa36cec-185e-4087-886b-a8bf81e81a75'	System	04 Oct 2020 20:50:39
User entered 'No (N)'	System	04 Oct 2020 20:50:39

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-04T15:50:37', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '9aa36cec-185e-4087-886b-a8bf81e81a75'	System	04 Oct 2020 20:50:39
User entered '04 Oct 2020 15:50'	System	04 Oct 2020 20:50:39

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 7'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-05T14:57:20', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b9d6ae2e-dd79-4930-9a34-a7ec10987b5f'	System	05 Oct 2020 19:57:36
User entered 'Yes (Y)'	System	05 Oct 2020 19:57:36

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-05T14:57:23', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b9d6ae2e-dd79-4930-9a34-a7ec10987b5f'	System	05 Oct 2020 19:57:36
User entered '97.4'	System	05 Oct 2020 19:57:36

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-05T14:57:26', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b9d6ae2e-dd79-4930-9a34-a7ec10987b5f'	System	05 Oct 2020 19:57:36
User entered 'No (N)'	System	05 Oct 2020 19:57:36

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-05T14:57:31', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b9d6ae2e-dd79-4930-9a34-a7ec10987b5f' User entered '05 Oct 2020 14:57'	System	05 Oct 2020 19:57:36
	System	05 Oct 2020 19:57:36

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T13:29:07', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '9282ad7c-181e-4a67-87a1-6ad4678cc415'	System	29 Sep 2020 18:29:26
User entered 'None (1)'	System	29 Sep 2020 18:29:26

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T13:29:10', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '9282ad7c-181e-4a67-87a1-6ad4678cc415'	System	29 Sep 2020 18:29:26
User entered 'No (N)'	System	29 Sep 2020 18:29:26

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T13:29:12', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '9282ad7c-181e-4a67-87a1-6ad4678cc415'	System	29 Sep 2020 18:29:26
User entered 'No (N)'	System	29 Sep 2020 18:29:26

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T13:29:18', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '9282ad7c-181e-4a67-87a1-6ad4678cc415'	System	29 Sep 2020 18:29:26
User entered 'None (1)'	System	29 Sep 2020 18:29:26

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T13:29:22', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '9282ad7c-181e-4a67-87a1-6ad4678cc415'	System	29 Sep 2020 18:29:26
User entered '29 Sep 2020 13:29'	System	29 Sep 2020 18:29:26

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '29 Sep 2020 13:15'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '29 Sep 2020 15:45'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T18:21:17', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '5169f5fb-1923-432b-b010-f90c40e577f7'	System	29 Sep 2020 23:21:39
User entered 'None (1)'	System	29 Sep 2020 23:21:39

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T18:21:21', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '5169f5fb-1923-432b-b010-f90c40e577f7'	System	29 Sep 2020 23:21:39
User entered 'No (N)'	System	29 Sep 2020 23:21:39

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T18:21:24', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '5169f5fb-1923-432b-b010-f90c40e577f7'	System	29 Sep 2020 23:21:39
User entered 'No (N)'	System	29 Sep 2020 23:21:39

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T18:21:28', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '5169f5fb-1923-432b-b010-f90c40e577f7'	System	29 Sep 2020 23:21:39
User entered 'None (1)'	System	29 Sep 2020 23:21:39

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T18:21:35', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '5169f5fb-1923-432b-b010-f90c40e577f7'	System	29 Sep 2020 23:21:39
User entered '29 Sep 2020 18:21'	System	29 Sep 2020 23:21:39

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '29 Sep 2020 16:40'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 2'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-30T18:28:09', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '57675e7b-3cee-4e8a-a4fc-a2b626e2b55e'	System	30 Sep 2020 23:28:36
User entered 'None (1)'	System	30 Sep 2020 23:28:36

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-30T18:28:15', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '57675e7b-3cee-4e8a-a4fc-a2b626e2b55e'	System	30 Sep 2020 23:28:36
User entered 'No (N)'	System	30 Sep 2020 23:28:36

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-30T18:28:18', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '57675e7b-3cee-4e8a-a4fc-a2b626e2b55e'	System	30 Sep 2020 23:28:36
User entered 'No (N)'	System	30 Sep 2020 23:28:36

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-30T18:28:24', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '57675e7b-3cee-4e8a-a4fc-a2b626e2b55e'	System	30 Sep 2020 23:28:36
User entered 'None (1)'	System	30 Sep 2020 23:28:36

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-30T18:28:30', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '57675e7b-3cee-4e8a-a4fc-a2b626e2b55e'	System	30 Sep 2020 23:28:36
User entered '30 Sep 2020 18:28'	System	30 Sep 2020 23:28:36

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 3'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-01T17:11:40', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'd6757eb5-e2db-4850-9fbd-fda17036977c'	System	01 Oct 2020 22:11:55
User entered 'None (1)'	System	01 Oct 2020 22:11:55

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-01T17:11:43', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'd6757eb5-e2db-4850-9fbd-fda17036977c'	System	01 Oct 2020 22:11:55
User entered 'No (N)'	System	01 Oct 2020 22:11:55

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-01T17:11:45', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'd6757eb5-e2db-4850-9fbd-fda17036977c'	System	01 Oct 2020 22:11:55
User entered 'No (N)'	System	01 Oct 2020 22:11:55

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-01T17:11:48', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'd6757eb5-e2db-4850-9fbd-fda17036977c'	System	01 Oct 2020 22:11:55
User entered 'None (1)'	System	01 Oct 2020 22:11:55

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-01T17:11:53', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'd6757eb5-e2db-4850-9fbd-fda17036977c'	System	01 Oct 2020 22:11:55
User entered '01 Oct 2020 17:11'	System	01 Oct 2020 22:11:55

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 4'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-02T18:13:30', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8a584655-dfb8-4631-9cfb-ab90e92a3ad1'	System	02 Oct 2020 23:13:49
User entered 'None (1)'	System	02 Oct 2020 23:13:49

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-02T18:13:33', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8a584655-dfb8-4631-9cfb-ab90e92a3ad1'	System	02 Oct 2020 23:13:49
User entered 'No (N)'	System	02 Oct 2020 23:13:49

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-02T18:13:35', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8a584655-dfb8-4631-9cfb-ab90e92a3ad1'	System	02 Oct 2020 23:13:49
User entered 'No (N)'	System	02 Oct 2020 23:13:49

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-02T18:13:39', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8a584655-dfb8-4631-9cfb-ab90e92a3ad1'	System	02 Oct 2020 23:13:49
User entered 'None (1)'	System	02 Oct 2020 23:13:49

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-02T18:13:44', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8a584655-dfb8-4631-9cfb-ab90e92a3ad1'	System	02 Oct 2020 23:13:49
User entered '02 Oct 2020 18:13'	System	02 Oct 2020 23:13:49

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 5'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-03T16:43:40', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'beb277a7-ae92-478e-bc73-9a7f0990c083'	System	03 Oct 2020 21:44:00
User entered 'None (1)'	System	03 Oct 2020 21:44:00

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-03T16:43:42', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'beb277a7-ae92-478e-bc73-9a7f0990c083'	System	03 Oct 2020 21:44:00
User entered 'No (N)'	System	03 Oct 2020 21:44:00

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-03T16:43:45', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'beb277a7-ae92-478e-bc73-9a7f0990c083'	System	03 Oct 2020 21:44:00
User entered 'No (N)'	System	03 Oct 2020 21:44:00

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-03T16:43:48', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'beb277a7-ae92-478e-bc73-9a7f0990c083'	System	03 Oct 2020 21:44:00
User entered 'None (1)'	System	03 Oct 2020 21:44:00

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-03T16:43:56', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'beb277a7-ae92-478e-bc73-9a7f0990c083'	System	03 Oct 2020 21:44:00
User entered '03 Oct 2020 16:43'	System	03 Oct 2020 21:44:00

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 6'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-04T15:50:41', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'ef284a27-f908-443f-826e-ed854ab31bce'	System	04 Oct 2020 20:50:59
User entered 'None (1)'	System	04 Oct 2020 20:50:59

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-04T15:50:44', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'ef284a27-f908-443f-826e-ed854ab31bce'	System	04 Oct 2020 20:50:59
User entered 'No (N)'	System	04 Oct 2020 20:50:59

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-04T15:50:46', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'ef284a27-f908-443f-826e-ed854ab31bce'	System	04 Oct 2020 20:50:59
User entered 'No (N)'	System	04 Oct 2020 20:50:59

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-04T15:50:50', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'ef284a27-f908-443f-826e-ed854ab31bce'	System	04 Oct 2020 20:50:59
User entered 'None (1)'	System	04 Oct 2020 20:50:59

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-04T15:50:55', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'ef284a27-f908-443f-826e-ed854ab31bce'	System	04 Oct 2020 20:50:59
User entered '04 Oct 2020 15:50'	System	04 Oct 2020 20:50:59

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 7'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-05T14:57:35', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'e8a86a41-5237-4a7f-a788-c19b65470d49'	System	05 Oct 2020 19:57:49
User entered 'None (1)'	System	05 Oct 2020 19:57:49

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-05T14:57:37', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'e8a86a41-5237-4a7f-a788-c19b65470d49'	System	05 Oct 2020 19:57:49
User entered 'No (N)'	System	05 Oct 2020 19:57:49

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-05T14:57:39', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'e8a86a41-5237-4a7f-a788-c19b65470d49'	System	05 Oct 2020 19:57:49
User entered 'No (N)'	System	05 Oct 2020 19:57:49

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-05T14:57:42', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'e8a86a41-5237-4a7f-a788-c19b65470d49'	System	05 Oct 2020 19:57:49
User entered 'None (1)'	System	05 Oct 2020 19:57:49

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-05T14:57:46', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'e8a86a41-5237-4a7f-a788-c19b65470d49'	System	05 Oct 2020 19:57:49
User entered '05 Oct 2020 14:57'	System	05 Oct 2020 19:57:49

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T13:29:27', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '42e587ea-fd8b-4b59-8658-5cc2f210b704'	System	29 Sep 2020 18:29:45
User entered 'None (0)'	System	29 Sep 2020 18:29:45

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T13:29:29', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '42e587ea-fd8b-4b59-8658-5cc2f210b704'	System	29 Sep 2020 18:29:45
User entered 'None (0)'	System	29 Sep 2020 18:29:45

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T13:29:31', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '42e587ea-fd8b-4b59-8658-5cc2f210b704'	System	29 Sep 2020 18:29:45
User entered 'None (0)'	System	29 Sep 2020 18:29:45

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T13:29:33', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '42e587ea-fd8b-4b59-8658-5cc2f210b704'	System	29 Sep 2020 18:29:45
User entered 'None (0)'	System	29 Sep 2020 18:29:45

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T13:29:35', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '42e587ea-fd8b-4b59-8658-5cc2f210b704'	System	29 Sep 2020 18:29:45
User entered 'None (0)'	System	29 Sep 2020 18:29:45

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T13:29:36', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '42e587ea-fd8b-4b59-8658-5cc2f210b704'	System	29 Sep 2020 18:29:45
User entered 'None (0)'	System	29 Sep 2020 18:29:45

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T13:29:39', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '42e587ea-fd8b-4b59-8658-5cc2f210b704'	System	29 Sep 2020 18:29:45
User entered 'No (N)'	System	29 Sep 2020 18:29:45

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T13:29:42', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '42e587ea-fd8b-4b59-8658-5cc2f210b704'	System	29 Sep 2020 18:29:45
User entered '29 Sep 2020 13:29'	System	29 Sep 2020 18:29:45

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '29 Sep 2020 13:15'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '29 Sep 2020 15:45'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T18:21:40', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '465b4291-3bd1-4d09-8148-1d6ae00abc07'	System	29 Sep 2020 23:22:06
User entered 'None (0)'	System	29 Sep 2020 23:22:06

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T18:21:43', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '465b4291-3bd1-4d09-8148-1d6ae00abc07'	System	29 Sep 2020 23:22:06
User entered 'None (0)'	System	29 Sep 2020 23:22:06

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T18:21:46', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '465b4291-3bd1-4d09-8148-1d6ae00abc07'	System	29 Sep 2020 23:22:06
User entered 'None (0)'	System	29 Sep 2020 23:22:06

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T18:21:49', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '465b4291-3bd1-4d09-8148-1d6ae00abc07'	System	29 Sep 2020 23:22:06
User entered 'None (0)'	System	29 Sep 2020 23:22:06

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T18:21:51', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '465b4291-3bd1-4d09-8148-1d6ae00abc07'	System	29 Sep 2020 23:22:06
User entered 'None (0)'	System	29 Sep 2020 23:22:06

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T18:21:53', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '465b4291-3bd1-4d09-8148-1d6ae00abc07'	System	29 Sep 2020 23:22:06
User entered 'None (0)'	System	29 Sep 2020 23:22:06

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T18:21:56', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '465b4291-3bd1-4d09-8148-1d6ae00abc07'	System	29 Sep 2020 23:22:06
User entered 'No (N)'	System	29 Sep 2020 23:22:06

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-29T18:22:02', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '465b4291-3bd1-4d09-8148-1d6ae00abc07'	System	29 Sep 2020 23:22:06
User entered '29 Sep 2020 18:22'	System	29 Sep 2020 23:22:06

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '29 Sep 2020 16:40'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 2'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-30T18:28:34', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'a063922a-ec96-4c6e-b0e5-2488e30b0c0a'	System	30 Sep 2020 23:28:59
User entered 'None (0)'	System	30 Sep 2020 23:28:59

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-30T18:28:37', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'a063922a-ec96-4c6e-b0e5-2488e30b0c0a'	System	30 Sep 2020 23:28:59
User entered 'None (0)'	System	30 Sep 2020 23:28:59

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-30T18:28:40', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'a063922a-ec96-4c6e-b0e5-2488e30b0c0a'	System	30 Sep 2020 23:28:59
User entered 'None (0)'	System	30 Sep 2020 23:28:59

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-30T18:28:42', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'a063922a-ec96-4c6e-b0e5-2488e30b0c0a'	System	30 Sep 2020 23:28:59
User entered 'None (0)'	System	30 Sep 2020 23:28:59

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-30T18:28:44', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'a063922a-ec96-4c6e-b0e5-2488e30b0c0a'	System	30 Sep 2020 23:28:59
User entered 'None (0)'	System	30 Sep 2020 23:28:59

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-30T18:28:46', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'a063922a-ec96-4c6e-b0e5-2488e30b0c0a'	System	30 Sep 2020 23:28:59
User entered 'None (0)'	System	30 Sep 2020 23:28:59

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-30T18:28:49', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'a063922a-ec96-4c6e-b0e5-2488e30b0c0a'	System	30 Sep 2020 23:28:59
User entered 'No (N)'	System	30 Sep 2020 23:28:59

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-09-30T18:28:55', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'a063922a-ec96-4c6e-b0e5-2488e30b0c0a'	System	30 Sep 2020 23:28:59
User entered '30 Sep 2020 18:28'	System	30 Sep 2020 23:28:59

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 3'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-01T17:11:57', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'fec3c3c6-4ac4-40c3-86c7-5bb778ac2fc6'	System	01 Oct 2020 22:12:21
User entered 'None (0)'	System	01 Oct 2020 22:12:21

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-01T17:12:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'fec3c3c6-4ac4-40c3-86c7-5bb778ac2fc6'	System	01 Oct 2020 22:12:21
User entered 'None (0)'	System	01 Oct 2020 22:12:21

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-01T17:12:01', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'fec3c3c6-4ac4-40c3-86c7-5bb778ac2fc6'	System	01 Oct 2020 22:12:21
User entered 'None (0)'	System	01 Oct 2020 22:12:21

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-01T17:12:04', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'fec3c3c6-4ac4-40c3-86c7-5bb778ac2fc6'	System	01 Oct 2020 22:12:21
User entered 'None (0)'	System	01 Oct 2020 22:12:21

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-01T17:12:06', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'fec3c3c6-4ac4-40c3-86c7-5bb778ac2fc6'	System	01 Oct 2020 22:12:21
User entered 'None (0)'	System	01 Oct 2020 22:12:21

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-01T17:12:08', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'fec3c3c6-4ac4-40c3-86c7-5bb778ac2fc6'	System	01 Oct 2020 22:12:21
User entered 'None (0)'	System	01 Oct 2020 22:12:21

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-01T17:12:10', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'fec3c3c6-4ac4-40c3-86c7-5bb778ac2fc6'	System	01 Oct 2020 22:12:21
User entered 'No (N)'	System	01 Oct 2020 22:12:21

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-01T17:12:15', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'fec3c3c6-4ac4-40c3-86c7-5bb778ac2fc6'	System	01 Oct 2020 22:12:21
User entered '01 Oct 2020 17:12'	System	01 Oct 2020 22:12:21

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 4'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-02T18:13:48', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '057faa6c-3887-4870-82ca-4f7c01977126'	System	02 Oct 2020 23:14:12
User entered 'None (0)'	System	02 Oct 2020 23:14:12

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-02T18:13:50', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '057faa6c-3887-4870-82ca-4f7c01977126'	System	02 Oct 2020 23:14:12
User entered 'None (0)'	System	02 Oct 2020 23:14:12

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-02T18:13:52', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '057faa6c-3887-4870-82ca-4f7c01977126'	System	02 Oct 2020 23:14:12
User entered 'None (0)'	System	02 Oct 2020 23:14:12

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-02T18:13:54', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '057faa6c-3887-4870-82ca-4f7c01977126'	System	02 Oct 2020 23:14:12
User entered 'None (0)'	System	02 Oct 2020 23:14:12

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-02T18:13:56', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '057faa6c-3887-4870-82ca-4f7c01977126'	System	02 Oct 2020 23:14:12
User entered 'None (0)'	System	02 Oct 2020 23:14:12

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-02T18:13:58', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '057faa6c-3887-4870-82ca-4f7c01977126'	System	02 Oct 2020 23:14:12
User entered 'None (0)'	System	02 Oct 2020 23:14:12

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-02T18:14:01', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '057faa6c-3887-4870-82ca-4f7c01977126'	System	02 Oct 2020 23:14:12
User entered 'No (N)'	System	02 Oct 2020 23:14:12

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-02T18:14:07', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '057faa6c-3887-4870-82ca-4f7c01977126'	System	02 Oct 2020 23:14:12
User entered '02 Oct 2020 18:14'	System	02 Oct 2020 23:14:12

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 5'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-03T16:44:01', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b93a61a1-04ec-4a04-9da9-de28514b2dbd'	System	03 Oct 2020 21:44:22
User entered 'None (0)'	System	03 Oct 2020 21:44:22

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-03T16:44:04', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b93a61a1-04ec-4a04-9da9-de28514b2dbd'	System	03 Oct 2020 21:44:22
User entered 'None (0)'	System	03 Oct 2020 21:44:22

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-03T16:44:06', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b93a61a1-04ec-4a04-9da9-de28514b2dbd'	System	03 Oct 2020 21:44:22
User entered 'None (0)'	System	03 Oct 2020 21:44:22

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-03T16:44:08', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b93a61a1-04ec-4a04-9da9-de28514b2dbd'	System	03 Oct 2020 21:44:22
User entered 'None (0)'	System	03 Oct 2020 21:44:22

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-03T16:44:10', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b93a61a1-04ec-4a04-9da9-de28514b2dbd'	System	03 Oct 2020 21:44:22
User entered 'None (0)'	System	03 Oct 2020 21:44:22

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-03T16:44:12', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b93a61a1-04ec-4a04-9da9-de28514b2dbd'	System	03 Oct 2020 21:44:22
User entered 'None (0)'	System	03 Oct 2020 21:44:22

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-03T16:44:14', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b93a61a1-04ec-4a04-9da9-de28514b2dbd'	System	03 Oct 2020 21:44:22
User entered 'No (N)'	System	03 Oct 2020 21:44:22

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-03T16:44:19', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b93a61a1-04ec-4a04-9da9-de28514b2dbd'	System	03 Oct 2020 21:44:22
User entered '03 Oct 2020 16:44'	System	03 Oct 2020 21:44:22

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 6'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-04T15:51:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b3a58192-9ce3-4b4b-b826-17a51c0963b5'	System	04 Oct 2020 20:51:17
User entered 'None (0)'	System	04 Oct 2020 20:51:17

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-04T15:51:02', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b3a58192-9ce3-4b4b-b826-17a51c0963b5'	System	04 Oct 2020 20:51:17
User entered 'None (0)'	System	04 Oct 2020 20:51:17

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-04T15:51:04', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b3a58192-9ce3-4b4b-b826-17a51c0963b5'	System	04 Oct 2020 20:51:17
User entered 'None (0)'	System	04 Oct 2020 20:51:17

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-04T15:51:05', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b3a58192-9ce3-4b4b-b826-17a51c0963b5'	System	04 Oct 2020 20:51:17
User entered 'None (0)'	System	04 Oct 2020 20:51:17

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-04T15:51:08', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b3a58192-9ce3-4b4b-b826-17a51c0963b5'	System	04 Oct 2020 20:51:17
User entered 'None (0)'	System	04 Oct 2020 20:51:17

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-04T15:51:10', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b3a58192-9ce3-4b4b-b826-17a51c0963b5'	System	04 Oct 2020 20:51:17
User entered 'None (0)'	System	04 Oct 2020 20:51:17

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-04T15:51:12', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b3a58192-9ce3-4b4b-b826-17a51c0963b5'	System	04 Oct 2020 20:51:17
User entered 'No (N)'	System	04 Oct 2020 20:51:17

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-04T15:51:14', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b3a58192-9ce3-4b4b-b826-17a51c0963b5'	System	04 Oct 2020 20:51:17
User entered '04 Oct 2020 15:51'	System	04 Oct 2020 20:51:17

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	29 Sep 2020 18:02:32
User entered 'Day 7'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-05T14:57:49', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c8a15a0b-0eac-473d-9250-3ef433365e3f'	System	05 Oct 2020 19:58:07
User entered 'None (0)'	System	05 Oct 2020 19:58:07

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-05T14:57:51', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c8a15a0b-0eac-473d-9250-3ef433365e3f'	System	05 Oct 2020 19:58:07
User entered 'None (0)'	System	05 Oct 2020 19:58:07

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-05T14:57:53', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c8a15a0b-0eac-473d-9250-3ef433365e3f'	System	05 Oct 2020 19:58:07
User entered 'None (0)'	System	05 Oct 2020 19:58:07

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-05T14:57:55', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c8a15a0b-0eac-473d-9250-3ef433365e3f'	System	05 Oct 2020 19:58:07
User entered 'None (0)'	System	05 Oct 2020 19:58:07

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-05T14:57:57', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c8a15a0b-0eac-473d-9250-3ef433365e3f'	System	05 Oct 2020 19:58:07
User entered 'None (0)'	System	05 Oct 2020 19:58:07

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-05T14:57:59', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c8a15a0b-0eac-473d-9250-3ef433365e3f'	System	05 Oct 2020 19:58:07
User entered 'None (0)'	System	05 Oct 2020 19:58:07

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-05T14:58:01', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c8a15a0b-0eac-473d-9250-3ef433365e3f'	System	05 Oct 2020 19:58:07
User entered 'No (N)'	System	05 Oct 2020 19:58:07

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-10-05T14:58:04', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'c8a15a0b-0eac-473d-9250-3ef433365e3f'	System	05 Oct 2020 19:58:07
User entered '05 Oct 2020 14:58'	System	05 Oct 2020 19:58:07

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 18:02:32

US3312434

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 18:02:32

US3312434

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:57:10

US3312434

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '6 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:57:10

US3312434

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:57:10

US3312434

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:57:10

US3312434

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:57:15

US3312434

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered 'I'	System	08 Oct 2020 18:57:15

US3312434

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:57

US3312434

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:57

US3312434

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:57

US3312434

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:57

US3312434

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:21

US3312434

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered 'I'	System	14 Oct 2020 18:50:21

US3312434

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:10:36

US3312434

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '20 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:10:36

US3312434

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:10:36

US3312434

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:10:36

US3312434

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:10:45

US3312434

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered 'I'	System	29 Oct 2020 13:10:45

US3312434

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:16:55

US3312434

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:16:55

US3312434

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:16:55

US3312434

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered 'VISIT3'	System	29 Oct 2020 13:16:55

US3312434

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:17:44

US3312434

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:17:44

US3312434

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '11:10'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:17:44

US3312434

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered '27 Oct 2020 11:10'	System	29 Oct 2020 13:17:44

US3312434

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:17:44

US3312434

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:17:44

US3312434

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:17:44

US3312434

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '71'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:17:44

US3312434

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered 'bpm'	System	29 Oct 2020 13:17:44

US3312434

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '14'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:17:44

US3312434

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered 'breaths/min'	System	29 Oct 2020 13:17:44

US3312434

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '124'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:17:44

US3312434

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered 'mmHg'	System	29 Oct 2020 13:17:44

US3312434

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '69'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:17:44

US3312434

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered 'mmHg'	System	29 Oct 2020 13:17:44

US3312434

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02

US3312434

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02

US3312434

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:17:49

US3312434

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:17:49

US3312434

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:17:57

US3312434

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:17:57

US3312434

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered '11:25'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:17:57

US3312434

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered '27 Oct 2020 11:25'	System	29 Oct 2020 13:17:57

US3312434

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:48:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 13:17:59

US3312434

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered 'I'	System	29 Oct 2020 13:17:59

US3312434

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 64'	System	01 Sep 2020 18:27:49

US3312434

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-11-01T06:14:39', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'ac67b9d6-7066-4ff9-a6ee-dbed70810743'	System	01 Nov 2020 12:15:04
User entered 'No (N)'	System	01 Nov 2020 12:15:04

US3312434

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Have you been exposed to someone with 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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-11-01T06:14:45', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'ac67b9d6-7066-4ff9-a6ee-dbed70810743'	System	01 Nov 2020 12:15:04
User entered 'No (N)'	System	01 Nov 2020 12:15:04

US3312434

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-11-01T06:14:59', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'ac67b9d6-7066-4ff9-a6ee-dbed70810743'	System	01 Nov 2020 12:15:04
User entered '01 Nov 2020 06:14:59'	System	01 Nov 2020 12:15:04

US3312434

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered '01 Nov 2020 00:01'	System	01 Sep 2020 18:27:49

US3312434

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered '05 Nov 2020 23:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 71'	System	01 Sep 2020 18:27:49

US3312434

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-11-08T08:57:33', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '70291701-8c09-4c49-b638-863dc8950066'	System	08 Nov 2020 14:57:55
User entered 'No (N)'	System	08 Nov 2020 14:57:55

US3312434

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Have you been exposed to someone with 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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-11-08T08:57:41', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '70291701-8c09-4c49-b638-863dc8950066'	System	08 Nov 2020 14:57:55
User entered 'No (N)'	System	08 Nov 2020 14:57:55

US3312434

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-11-08T08:57:52', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '70291701-8c09-4c49-b638-863dc8950066'	System	08 Nov 2020 14:57:55
User entered '08 Nov 2020 08:57:52'	System	08 Nov 2020 14:57:55

US3312434

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered '08 Nov 2020 00:01'	System	01 Sep 2020 18:27:49

US3312434

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered '12 Nov 2020 23:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered 'Day 78'	System	01 Sep 2020 18:27:49

US3312434

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-11-15T07:34:07', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '3bc32afa-8cfc-422c-8c33-dc8cd4bd9a05'	System	15 Nov 2020 13:34:20
User entered 'No (N)'	System	15 Nov 2020 13:34:20

US3312434

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Have you been exposed to someone with 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 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-11-15T07:34:12', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '3bc32afa-8cfc-422c-8c33-dc8cd4bd9a05'	System	15 Nov 2020 13:34:20
User entered 'No (N)'	System	15 Nov 2020 13:34:20

US3312434

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-11-15T07:34:18', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '3bc32afa-8cfc-422c-8c33-dc8cd4bd9a05'	System	15 Nov 2020 13:34:20
User entered '15 Nov 2020 07:34:18'	System	15 Nov 2020 13:34:20

US3312434

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered '15 Nov 2020 00:01'	System	01 Sep 2020 18:27:49

US3312434

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:43:16
Data entry locked.	System	01 Sep 2020 18:27:49
User entered '19 Nov 2020 23:59'	System	01 Sep 2020 18:27:49

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[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 (5f457b7b47a057f5)', Time: '2020-12-03T07:26:58', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '2c76bba8-720c-4f26-9c58-221d043e0820'	System	03 Dec 2020 13:27:13
User entered 'No (N)'	System	03 Dec 2020 13:27:13

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Have you been exposed to someone with 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 (5f457b7b47a057f5)', Time: '2020-12-03T07:27:03', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '2c76bba8-720c-4f26-9c58-221d043e0820'	System	03 Dec 2020 13:27:13
User entered 'No (N)'	System	03 Dec 2020 13:27:13

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-12-03T07:27:09', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '2c76bba8-720c-4f26-9c58-221d043e0820'	System	03 Dec 2020 13:27:13
User entered '03 Dec 2020 07:27:09'	System	03 Dec 2020 13:27:13

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[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 (5f457b7b47a057f5)', Time: '2020-12-10T06:36:04', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8a2dc643-dcbe-4f99-a02c-f043ed1a36df'	System	10 Dec 2020 12:36:18
User entered 'No (N)'	System	10 Dec 2020 12:36:18

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Have you been exposed to someone with 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 (5f457b7b47a057f5)', Time: '2020-12-10T06:36:10', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8a2dc643-dcbe-4f99-a02c-f043ed1a36df'	System	10 Dec 2020 12:36:18
User entered 'No (N)'	System	10 Dec 2020 12:36:18

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-12-10T06:36:15', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '8a2dc643-dcbe-4f99-a02c-f043ed1a36df'	System	10 Dec 2020 12:36:18
User entered '10 Dec 2020 06:36:15'	System	10 Dec 2020 12:36:18

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[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 (5f457b7b47a057f5)', Time: '2020-12-17T07:12:02', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '86abbc16-8693-42d8-a541-a833d62c6c07'	System	17 Dec 2020 13:12:16
User entered 'No (N)'	System	17 Dec 2020 13:12:16

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Have you been exposed to someone with 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 (5f457b7b47a057f5)', Time: '2020-12-17T07:12:08', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '86abbc16-8693-42d8-a541-a833d62c6c07'	System	17 Dec 2020 13:12:16
User entered 'No (N)'	System	17 Dec 2020 13:12:16

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-12-17T07:12:13', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '86abbc16-8693-42d8-a541-a833d62c6c07'	System	17 Dec 2020 13:12:16
User entered '17 Dec 2020 07:12:13'	System	17 Dec 2020 13:12:16

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[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 (5f457b7b47a057f5)', Time: '2020-12-31T07:20:30', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '7ebae246-5a3a-44c2-9553-f85293695b93'	System	31 Dec 2020 13:20:43
User entered 'No (N)'	System	31 Dec 2020 13:20:43

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Have you been exposed to someone with 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 (5f457b7b47a057f5)', Time: '2020-12-31T07:20:35', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '7ebae246-5a3a-44c2-9553-f85293695b93'	System	31 Dec 2020 13:20:43
User entered 'No (N)'	System	31 Dec 2020 13:20:43

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2020-12-31T07:20:39', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '7ebae246-5a3a-44c2-9553-f85293695b93'	System	31 Dec 2020 13:20:43
User entered '31 Dec 2020 07:20:39'	System	31 Dec 2020 13:20:43

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[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 (5f457b7b47a057f5)', Time: '2021-01-14T06:48:02', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'f1a758d9-f8f3-44b2-b9dd-bdb34339ecf2'	System	14 Jan 2021 12:48:16
User entered 'No (N)'	System	14 Jan 2021 12:48:16

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Have you been exposed to someone with 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 (5f457b7b47a057f5)', Time: '2021-01-14T06:48:06', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'f1a758d9-f8f3-44b2-b9dd-bdb34339ecf2'	System	14 Jan 2021 12:48:16
User entered 'No (N)'	System	14 Jan 2021 12:48:16

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2021-01-14T06:48:13', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'f1a758d9-f8f3-44b2-b9dd-bdb34339ecf2' User entered '14 Jan 2021 06:48:13'	System	14 Jan 2021 12:48:16

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[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 (5f457b7b47a057f5)', Time: '2021-01-21T06:33:12', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '3c008fde-b901-45c7-9958-5211942bcc27'	System	21 Jan 2021 12:33:26
User entered 'No (N)'	System	21 Jan 2021 12:33:26

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Have you been exposed to someone with 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 (5f457b7b47a057f5)', Time: '2021-01-21T06:33:17', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '3c008fde-b901-45c7-9958-5211942bcc27'	System	21 Jan 2021 12:33:26
User entered 'No (N)'	System	21 Jan 2021 12:33:26

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2021-01-21T06:33:22', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '3c008fde-b901-45c7-9958-5211942bcc27'	System	21 Jan 2021 12:33:26
User entered '21 Jan 2021 06:33:22'	System	21 Jan 2021 12:33:26

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[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 (5f457b7b47a057f5)', Time: '2021-01-28T06:49:50', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'ae011ed8-4f15-44aa-8f5b-de08f6117fc9'	System	28 Jan 2021 12:50:06
User entered 'No (N)'	System	28 Jan 2021 12:50:06

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Have you been exposed to someone with 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 (5f457b7b47a057f5)', Time: '2021-01-28T06:49:55', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'ae011ed8-4f15-44aa-8f5b-de08f6117fc9'	System	28 Jan 2021 12:50:06
User entered 'No (N)'	System	28 Jan 2021 12:50:06

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2021-01-28T06:50:03', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'ae011ed8-4f15-44aa-8f5b-de08f6117fc9'	System	28 Jan 2021 12:50:06
User entered '28 Jan 2021 06:50:03'	System	28 Jan 2021 12:50:06

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[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 (5f457b7b47a057f5)', Time: '2021-02-04T08:42:40', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '183cd7d7-4cbd-4f0b-bcff-69bb3154c77e'	System	04 Feb 2021 14:43:10
User entered 'No (N)'	System	04 Feb 2021 14:43:10

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Have you been exposed to someone with 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 (5f457b7b47a057f5)', Time: '2021-02-04T08:42:37', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '183cd7d7-4cbd-4f0b-bcff-69bb3154c77e'	System	04 Feb 2021 14:43:10
User entered 'No (N)'	System	04 Feb 2021 14:43:10

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2021-02-04T08:43:05', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '183cd7d7-4cbd-4f0b-bcff-69bb3154c77e'	System	04 Feb 2021 14:43:10
User entered '04 Feb 2021 08:43:05'	System	04 Feb 2021 14:43:10

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[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 (5f457b7b47a057f5)', Time: '2021-02-11T07:05:02', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b481f16d-10b9-490b-9f63-aa27fe1030a0'	System	11 Feb 2021 13:05:13
User entered 'No (N)'	System	11 Feb 2021 13:05:13

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Have you been exposed to someone with 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 (5f457b7b47a057f5)', Time: '2021-02-11T07:05:05', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b481f16d-10b9-490b-9f63-aa27fe1030a0'	System	11 Feb 2021 13:05:13
User entered 'No (N)'	System	11 Feb 2021 13:05:13

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2021-02-11T07:05:10', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b481f16d-10b9-490b-9f63-aa27fe1030a0'	System	11 Feb 2021 13:05:13
User entered '11 Feb 2021 07:05:10'	System	11 Feb 2021 13:05:13

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[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 (5f457b7b47a057f5)', Time: '2021-02-18T08:43:39', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'e08322d7-8046-4282-ba6c-c78900f81e43'	System	18 Feb 2021 14:43:55
User entered 'No (N)'	System	18 Feb 2021 14:43:55

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Have you been exposed to someone with 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 (5f457b7b47a057f5)', Time: '2021-02-18T08:43:44', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'e08322d7-8046-4282-ba6c-c78900f81e43'	System	18 Feb 2021 14:43:55
User entered 'No (N)'	System	18 Feb 2021 14:43:55

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2021-02-18T08:43:51', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'e08322d7-8046-4282-ba6c-c78900f81e43'	System	18 Feb 2021 14:43:55
User entered '18 Feb 2021 08:43:51'	System	18 Feb 2021 14:43:55

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[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 (5f457b7b47a057f5)', Time: '2021-02-26T14:14:26-06:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '01122ff9-1ae5-4859-81d7-4d3af9b981ff' User entered 'No (N)'	System	26 Feb 2021 20:14:37
	System	26 Feb 2021 20:14:37

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Have you been exposed to someone with 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 (5f457b7b47a057f5)', Time: '2021-02-26T14:14:29-06:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '01122ff9-1ae5-4859-81d7-4d3af9b981ff' User entered 'No (N)'	System	26 Feb 2021 20:14:37

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2021-02-26T14:14:33-06:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '01122ff9-1ae5-4859-81d7-4d3af9b981ff' User entered '26 Feb 2021 14:14:33'	System	26 Feb 2021 20:14:37
	System	26 Feb 2021 20:14:37

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[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 (5f457b7b47a057f5)', Time: '2021-03-04T07:14:58-06:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'd5b29dd3-42d0-47ca-97a6-96aedc00c6b9'	System	04 Mar 2021 13:15:13
User entered 'No (N)'	System	04 Mar 2021 13:15:13

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Have you been exposed to someone with 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 (5f457b7b47a057f5)', Time: '2021-03-04T07:15:02-06:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'd5b29dd3-42d0-47ca-97a6-96aedc00c6b9'	System	04 Mar 2021 13:15:13
User entered 'No (N)'	System	04 Mar 2021 13:15:13

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2021-03-04T07:15:09-06:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'd5b29dd3-42d0-47ca-97a6-96aedc00c6b9'	System	04 Mar 2021 13:15:13
User entered '04 Mar 2021 07:15:09'	System	04 Mar 2021 13:15:13

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[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 (5f457b7b47a057f5)', Time: '2021-03-12T12:00:09-06:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '1248b6fc-d8f9-4744-a60e-4001ffe395b5'	System	12 Mar 2021 18:00:21
User entered 'No (N)'	System	12 Mar 2021 18:00:21

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Have you been exposed to someone with 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 (5f457b7b47a057f5)', Time: '2021-03-12T12:00:13-06:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '1248b6fc-d8f9-4744-a60e-4001ffe395b5'	System	12 Mar 2021 18:00:21
User entered 'No (N)'	System	12 Mar 2021 18:00:21

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2021-03-12T12:00:17-06:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '1248b6fc-d8f9-4744-a60e-4001ffe395b5'	System	12 Mar 2021 18:00:21
User entered '12 Mar 2021 12:00:17'	System	12 Mar 2021 18:00:21

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[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 (5f457b7b47a057f5)', Time: '2021-03-18T06:59:47-05:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '45a2005a-c94f-4f64-a278-f4aa422ba0e3'	System	18 Mar 2021 11:59:58
User entered 'No (N)'	System	18 Mar 2021 11:59:58

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Have you been exposed to someone with 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 (5f457b7b47a057f5)', Time: '2021-03-18T06:59:50-05:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '45a2005a-c94f-4f64-a278-f4aa422ba0e3'	System	18 Mar 2021 11:59:58
User entered 'No (N)'	System	18 Mar 2021 11:59:58

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2021-03-18T06:59:54-05:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '45a2005a-c94f-4f64-a278-f4aa422ba0e3' User entered '18 Mar 2021 06:59:54'	System	18 Mar 2021 11:59:58
	System	18 Mar 2021 11:59:58

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[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 (5f457b7b47a057f5)', Time: '2021-03-25T06:45:53-05:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'ca6b8dee-59ef-4480-8635-d176e2676649'	System	25 Mar 2021 11:46:05
User entered 'No (N)'	System	25 Mar 2021 11:46:05

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Have you been exposed to someone with 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 (5f457b7b47a057f5)', Time: '2021-03-25T06:45:57-05:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'ca6b8dee-59ef-4480-8635-d176e2676649'	System	25 Mar 2021 11:46:05
User entered 'No (N)'	System	25 Mar 2021 11:46:05

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2021-03-25T06:46:01-05:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'ca6b8dee-59ef-4480-8635-d176e2676649' User entered '25 Mar 2021 06:46:01'	System	25 Mar 2021 11:46:05
	System	25 Mar 2021 11:46:05

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[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 (5f457b7b47a057f5)', Time: '2021-04-01T06:52:42-05:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '965afa44-4a1f-40ed-b751-05fe322f9941' User entered 'No (N)'	System	01 Apr 2021 11:52:54
	System	01 Apr 2021 11:52:54

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Have you been exposed to someone with 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 (5f457b7b47a057f5)', Time: '2021-04-01T06:52:46-05:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '965afa44-4a1f-40ed-b751-05fe322f9941'	System	01 Apr 2021 11:52:54
User entered 'No (N)'	System	01 Apr 2021 11:52:54

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2021-04-01T06:52:50-05:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: '965afa44-4a1f-40ed-b751-05fe322f9941'	System	01 Apr 2021 11:52:54
User entered '01 Apr 2021 06:52:50'	System	01 Apr 2021 11:52:54

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[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 (5f457b7b47a057f5)', Time: '2021-04-08T09:34:16-05:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b5f8d0f9-7399-4b5d-a6e2-f9e6c0398416'	System	08 Apr 2021 14:34:55
User entered 'No (N)'	System	08 Apr 2021 14:34:55

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Have you been exposed to someone with 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 (5f457b7b47a057f5)', Time: '2021-04-08T09:34:47-05:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b5f8d0f9-7399-4b5d-a6e2-f9e6c0398416'	System	08 Apr 2021 14:34:55
User entered 'No (N)'	System	08 Apr 2021 14:34:55

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2021-04-08T09:34:51-05:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'b5f8d0f9-7399-4b5d-a6e2-f9e6c0398416'	System	08 Apr 2021 14:34:55
User entered '08 Apr 2021 09:34:51'	System	08 Apr 2021 14:34:55

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[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 (5f457b7b47a057f5)', Time: '2021-04-18T08:07:49-05:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'd212bd73-5a9f-42b7-ac75-28d6e55dd66b'	System	18 Apr 2021 13:08:01
User entered 'No (N)'	System	18 Apr 2021 13:08:01

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Have you been exposed to someone with 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 (5f457b7b47a057f5)', Time: '2021-04-18T08:07:52-05:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'd212bd73-5a9f-42b7-ac75-28d6e55dd66b'	System	18 Apr 2021 13:08:01
User entered 'No (N)'	System	18 Apr 2021 13:08:01

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2021-04-18T08:07:56-05:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'd212bd73-5a9f-42b7-ac75-28d6e55dd66b' User entered '18 Apr 2021 08:07:56'	System	18 Apr 2021 13:08:01
	System	18 Apr 2021 13:08:01

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[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 (5f457b7b47a057f5)', Time: '2021-04-22T06:53:53-05:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'abc9f7c8-f79b-4e95-8d6d-f82f98adb84b' User entered 'No (N)'	System	22 Apr 2021 11:54:07
	System	22 Apr 2021 11:54:07

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Have you been exposed to someone with 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 (5f457b7b47a057f5)', Time: '2021-04-22T06:53:56-05:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'abc9f7c8-f79b-4e95-8d6d-f82f98adb84b'	System	22 Apr 2021 11:54:07
User entered 'No (N)'	System	22 Apr 2021 11:54:07

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2021-04-22T06:54:00-05:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'abc9f7c8-f79b-4e95-8d6d-f82f98adb84b'	System	22 Apr 2021 11:54:07
User entered '22 Apr 2021 06:54:00'	System	22 Apr 2021 11:54:07

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[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 (5f457b7b47a057f5)', Time: '2021-04-29T07:00:01-05:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'e2185c55-35bb-444b-b8eb-b848b7b9ff57'	System	29 Apr 2021 12:00:12
User entered 'No (N)'	System	29 Apr 2021 12:00:12

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

Have you been exposed to someone with 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 (5f457b7b47a057f5)', Time: '2021-04-29T07:00:04-05:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'e2185c55-35bb-444b-b8eb-b848b7b9ff57'	System	29 Apr 2021 12:00:12
User entered 'No (N)'	System	29 Apr 2021 12:00:12

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2021-04-29T07:00:07-05:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'e2185c55-35bb-444b-b8eb-b848b7b9ff57'	System	29 Apr 2021 12:00:12
User entered '29 Apr 2021 07:00:07'	System	29 Apr 2021 12:00:12

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '03 Nov 2022 00:01'	System	19 Nov 2020 21:49:53

US3312434

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:49:53
Amendment Manager: User entered '07 Nov 2022 23:59'	System	19 Nov 2020 21:49:53

US3312434

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:02:25

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2021-03-02T17:50:23-06:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'e97d6c46-f0cb-428c-a67c-dd9f2ac7f129'	System	02 Mar 2021 23:50:38
User entered 'No (N)'	System	02 Mar 2021 23:50:38

US3312434

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:02:25

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f457b7b47a057f5)', Time: '2021-03-02T17:50:34-06:00', User OID: 'PatientReportedOutcome (US3312434)', ODM File OID: 'e97d6c46-f0cb-428c-a67c-dd9f2ac7f129'	System	02 Mar 2021 23:50:38
User entered '02 Mar 2021 17:50:34'	System	02 Mar 2021 23:50:38

US3312434

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	24 Nov 2020 20:48:57

US3312434

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '24 Nov 2020'	(b) (4) Kelly Moen (b) (4) (b) (4)	24 Nov 2020 20:48:57

US3312434

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelly Moen (b) (4) (b) (4)	24 Nov 2020 20:48:57

US3312434

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	24 Nov 2020 20:48:57

US3312434

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	24 Nov 2020 20:49:02

US3312434

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:35:02
User entered 'I'	System	24 Nov 2020 20:49:02

US3312434

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:52:23

US3312434

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '29 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:52:23

US3312434

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:52:23

US3312434

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:52:23

US3312434

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:52:06

US3312434

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User entered 'I'	System	29 Dec 2020 16:52:06

US3312434

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:53:16

US3312434

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:53:16

US3312434

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:53:16

US3312434

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:53:16

US3312434

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:53:06

US3312434

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User entered 'I'	System	26 Jan 2021 14:53:06

US3312434

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:34:44

US3312434

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:34:44

US3312434

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:34:44

US3312434

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:34:44

US3312434

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:34:47

US3312434

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User entered 'I'	System	25 Feb 2021 16:34:47

US3312434

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:26:10

US3312434

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:26:10

US3312434

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:26:10

US3312434

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User entered 'VISIT4'	System	19 Mar 2021 18:26:10

US3312434

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:52:03

US3312434

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:52:03

US3312434

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:52:03

US3312434

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User entered empty.	System	31 Mar 2021 13:52:03

US3312434

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:52:03

US3312434

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:52:03

US3312434

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:52:03

US3312434

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:52:03

US3312434

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User entered empty.	System	31 Mar 2021 13:52:03

US3312434

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:52:03

US3312434

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User entered empty.	System	31 Mar 2021 13:52:03

US3312434

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:52:03

US3312434

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User entered empty.	System	31 Mar 2021 13:52:03

US3312434

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:52:03

US3312434

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User entered empty.	System	31 Mar 2021 13:52:03

US3312434

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41

US3312434

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41

US3312434

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:26:19

US3312434

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:26:19

US3312434

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:26:40

US3312434

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:26:40

US3312434

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '10:49'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:26:40

US3312434

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User entered '19 Mar 2021 10:49'	System	19 Mar 2021 18:26:40

US3312434

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:25:55

US3312434

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:04:41
User entered 'I'	System	19 Mar 2021 18:25:55

US3312434

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

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 20:58:56

US3312434

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

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 20:58:56

US3312434

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

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 20:58:56

US3312434

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

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'UNBLND_DECIDE'	System	11 Jan 2021 20:58:56

US3312434

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

Form: Unblinding

Generated On: 09 Jun 2021 17:02:25

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:01:15

US3312434

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

Form: Unblinding

Generated On: 09 Jun 2021 17:02:25

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:28:52

US3312434

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

Form: Unblinding

Generated On: 09 Jun 2021 17:02:25

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:01:15

US3312434

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

Form: Unblinding

Generated On: 09 Jun 2021 17:02:25

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:28:52

US3312434

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

Form: Unblinding

Generated On: 09 Jun 2021 17:02:25

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:01:15

US3312434

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

Form: Unblinding

Generated On: 09 Jun 2021 17:02:25

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:01:15

US3312434

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

Form: Unblinding

Generated On: 09 Jun 2021 17:02:25

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 08:52:08
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	11 Jan 2021 21:01:15

US3312434

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

Form: Unblinding

Generated On: 09 Jun 2021 17:02:25

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 08:52:08
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	11 Jan 2021 21:01:15

US3312434

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

Form: Unblinding

Generated On: 09 Jun 2021 17:02:25

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:01:15

US3312434

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

Form: Unblinding

Generated On: 09 Jun 2021 17:02:25

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered '1'	System	11 Jan 2021 21:01:15

US3312434

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

Form: Unblinding

Generated On: 09 Jun 2021 17:02:25

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'I'	System	11 Jan 2021 21:01:15

US3312434

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:25

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered empty.	System	11 Jan 2021 21:03:17
DataPoint set to visible.	System	11 Jan 2021 21:01:15

US3312434

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered empty.	System	11 Jan 2021 21:03:17
DataPoint set to visible.	System	11 Jan 2021 21:01:15

US3312434

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '13:12'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered '11 Jan 2021 13:12'	System	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '68'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'bpm'	System	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '16'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'breaths/min'	System	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '136'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'mmHg'	System	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '84'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'mmHg'	System	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:25

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered empty.	System	11 Jan 2021 21:03:17
DataPoint set to visible.	System	11 Jan 2021 21:01:15

US3312434

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '14:35'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered '11 Jan 2021 14:35'	System	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '63'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'bpm'	System	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '14'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'breaths/min'	System	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '136'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'mmHg'	System	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '76'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:17

US3312434

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'mmHg'	System	11 Jan 2021 21:03:17

US3312434

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:26

US3312434

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:26

US3312434

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

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:42

US3312434

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

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:42

US3312434

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

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:42

US3312434

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

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'mRNA-1273'	System	11 Jan 2021 21:03:42
DataPoint set to visible.	System	11 Jan 2021 21:01:15

US3312434

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

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:42

US3312434

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

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '14:04'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:42

US3312434

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

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered '11 Jan 2021 14:04'	System	11 Jan 2021 21:03:42

US3312434

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

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:03:42

US3312434

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

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'ONCE'	System	11 Jan 2021 21:03:42

US3312434

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

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'INTRAMUSCULAR'	System	11 Jan 2021 21:03:42

US3312434

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:01:27

US3312434

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:01:27

US3312434

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '13:00'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:01:27

US3312434

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered '11 Jan 2021 13:00'	System	11 Jan 2021 21:01:27

US3312434

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:02:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:01:44

US3312434

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:02:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:01:44

US3312434

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '12:59'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:01:44

US3312434

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered '11 Jan 2021 12:59'	System	11 Jan 2021 21:01:44

US3312434

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

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:01:49

US3312434

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

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'I'	System	11 Jan 2021 21:01:49

US3312434

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:31:56

US3312434

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:31:56

US3312434

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:31:56

US3312434

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:31:56

US3312434

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:32:00

US3312434

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'I'	System	19 Jan 2021 15:32:00

US3312434

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered '1'	System	19 Jan 2021 15:32:00
DataPoint set to visible.	System	19 Jan 2021 15:32:00

US3312434

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:31:13

US3312434

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:31:13

US3312434

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:31:13

US3312434

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'OLD29'	System	25 Feb 2021 16:31:13

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '09:36'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered '19 Feb 2021 09:36'	System	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '63'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'bpm'	System	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '16'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'breaths/min'	System	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '133'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'mmHg'	System	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '75'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'mmHg'	System	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '11:06'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered '19 Feb 2021 11:06'	System	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '63'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'bpm'	System	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '16'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'breaths/min'	System	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '107'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'mmHg'	System	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	27 Feb 2021 05:37:22
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CONFIRMED CORRECT AS ENTERED. NCS NOT AN AE. DIASTOLIC LOW BP NOT ON TOXICITY TABLE. ' (Site from System).	(b) (4), (b) (6)	25 Feb 2021 16:33:18
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		25 Feb 2021 16:32:16
User entered '56'	(b) (4), (b) (6)	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'mmHg'	System	25 Feb 2021 16:32:16

US3312434

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:33:28

US3312434

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:25

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:33:28

US3312434

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:33:43

US3312434

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:33:43

US3312434

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:33:43

US3312434

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'mRNA-1273'	System	25 Feb 2021 16:33:43
DataPoint set to visible.	System	19 Jan 2021 15:32:00

US3312434

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:33:43

US3312434

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '10:35'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:33:43

US3312434

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered '19 Feb 2021 10:35'	System	25 Feb 2021 16:33:43

US3312434

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:33:43

US3312434

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'ONCE'	System	25 Feb 2021 16:33:43

US3312434

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'INTRAMUSCULAR'	System	25 Feb 2021 16:33:43

US3312434

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:33:46

US3312434

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'I'	System	25 Feb 2021 16:33:46

US3312434

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:03:06

US3312434

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:03:06

US3312434

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:03:06

US3312434

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:03:06

US3312434

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:03:09

US3312434

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'I'	System	02 Mar 2021 14:03:09

US3312434

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:26:55

US3312434

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:26:55

US3312434

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:26:55

US3312434

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered 'OLD57'	System	19 Mar 2021 18:26:55

US3312434

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User closed query 'Per CDM:Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" has no response of "Yes" or "No", but on OL-D57 it is recorded as "No". Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:15:13
Query 'Per CDM:Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" has no response of "Yes" or "No", but on OL-D57 it is recorded as "No". Please clarify why there is a difference or update the field. Thank you!' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	02 Apr 2021 14:27:13
User opened query 'Per CDM:Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" has no response of "Yes" or "No", but on OL-D57 it is recorded as "No". Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 14:06:34
User entered 'No (N)'	(b) (4), (b) (6)	19 Mar 2021 18:27:04

US3312434

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:27:04

US3312434

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:27:04

US3312434

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered empty.	System	19 Mar 2021 18:27:04

US3312434

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:27:04

US3312434

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:27:04

US3312434

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:27:04

US3312434

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:27:04

US3312434

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered empty.	System	19 Mar 2021 18:27:04

US3312434

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:27:04

US3312434

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered empty.	System	19 Mar 2021 18:27:04

US3312434

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:27:04

US3312434

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered empty.	System	19 Mar 2021 18:27:04

US3312434

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:27:04

US3312434

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered empty.	System	19 Mar 2021 18:27:04

US3312434

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20

US3312434

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20

US3312434

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:27:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 18:27:08

US3312434

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	(b) (4)	19 Mar 2021 18:27:13
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	19 Mar 2021 18:27:08
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 18:27:08

US3312434

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:27:26

US3312434

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:27:26

US3312434

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '10:49'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:27:26

US3312434

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:26:20
User entered '19 Mar 2021 10:49'	System	19 Mar 2021 18:27:26

US3312434

Folder: Unscheduled 01 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:02:25

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:27
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '01 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:29:06

US3312434

Folder: Unscheduled 01 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:02:25

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:27
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:29:06

US3312434

Folder: Unscheduled 01 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:02:25

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:27
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:29:06

US3312434

Folder: **Unscheduled 01 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:02:25**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:27
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:29:06

US3312434

Folder: Unscheduled 01 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:02:25

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:27
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:29:06

US3312434

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Yes (Y)'	(b) (4)	24 Sep 2020 16:29:26
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '01 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:29:26

US3312434

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '14:00'	(b) (4)	24 Sep 2020 16:29:26
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: **Unscheduled 01 Sep 2020**

Form: **Vital Signs**

Generated On: **09 Jun 2021 17:02:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:42
User entered '01 Sep 2020 14:00'	System	24 Sep 2020 16:29:26

US3312434

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:29:26

US3312434

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:29:26

US3312434

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered empty.	(b) (4)	24 Sep 2020 16:29:26
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:29:26

US3312434

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:42
User entered 'bpm'	System	24 Sep 2020 16:29:26

US3312434

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:29:26

US3312434

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:42
User entered 'breaths/min'	System	24 Sep 2020 16:29:26

US3312434

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '154'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:29:26

US3312434

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:42
User entered 'mmHg'	System	24 Sep 2020 16:29:26

US3312434

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '90'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:29:26

US3312434

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:42
User entered 'mmHg'	System	24 Sep 2020 16:29:26

US3312434

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:42

US3312434

Folder: Unscheduled 01 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:42

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:02:25

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:08:55
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '29 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:36:59

US3312434

Folder: **Unscheduled 29 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:02:25**

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:08:55
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:36:59

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:02:25

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:08:55
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:36:59

US3312434

Folder: **Unscheduled 29 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:02:25**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:08:55
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:36:59

US3312434

Folder: **Unscheduled 29 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:02:25**

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:08:55
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '0'	(b) (4)	17 Oct 2020 23:36:59
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:03
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:37:19

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:03
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '29 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:37:19

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:03
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '11:47'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:37:19

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:03
User entered '29 Sep 2020 11:47'	System	17 Oct 2020 23:37:19

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:03
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:37:19

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:03
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:37:19

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:03
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:37:19

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:03
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:37:19

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:03
User entered 'bpm'	System	17 Oct 2020 23:37:19

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:03
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:37:19

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:03
User entered 'breaths/min'	System	17 Oct 2020 23:37:19

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:03
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '157'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:37:19

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:03
User entered 'mmHg'	System	17 Oct 2020 23:37:19

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:03
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '79'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:37:19

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:03
User entered 'mmHg'	System	17 Oct 2020 23:37:19

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:03

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:09:03

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:02:25

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '29 Sep 2020'	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:37:30
	(b) (4)	

US3312434

Folder: **Unscheduled 29 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:02:25**

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '0'	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:37:30

US3312434

Folder: **Unscheduled 29 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:02:25**

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:37:30

US3312434

Folder: **Unscheduled 29 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:02:25**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '0'	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:37:30

US3312434

Folder: **Unscheduled 29 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:02:25**

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:42
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '0'	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:37:30

US3312434

Folder: **Unscheduled 29 Sep 2020**

Form: **Vital Signs**

Generated On: **09 Jun 2021 17:02:25**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:47
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:37:52

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:47
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '29 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:37:52

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:47
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '13:31'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:37:52

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:47
User entered '29 Sep 2020 13:31'	System	17 Oct 2020 23:37:52

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:47
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:37:52

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:47
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:37:52

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Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

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[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:47
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:37:52

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Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

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[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:47
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:37:52

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:47
User entered 'bpm'	System	17 Oct 2020 23:37:52

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Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:47
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:37:52

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Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:47
User entered 'breaths/min'	System	17 Oct 2020 23:37:52

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:47
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '158'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:37:52

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:47
User entered 'mmHg'	System	17 Oct 2020 23:37:52

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:47
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:33:29
User entered '87'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:37:52

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:47
User entered 'mmHg'	System	17 Oct 2020 23:37:52

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 22:48:47

US3312434

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:47

US3312434

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:02:25

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:26:04
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:01:37
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:09:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User closed query 'Per DM CLR: Please review AE and please update to specify the location/type of Congestion. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 11:46:57
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:08:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:08:32
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:07:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:07:31
Data point term sent to Coder	System	23 Oct 2020 19:07:26
Query 'Per DM CLR: Please review AE and please update to specify the location/type of Congestion. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	23 Oct 2020 19:06:29
User closed query 'DM-Coding: The verbatim CONGESTION cannot be referenced as reported. Please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding.' (Site from System).	System	23 Oct 2020 19:06:25
Query 'DM-Coding: The verbatim CONGESTION cannot be referenced as reported. Please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding.' answered with 'UPDATED' (Site from System).	Karol Moore (b) (4) (b) (4)	23 Oct 2020 19:06:25

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	23 Oct 2020 19:06:24
User entered 'nASAL CONGESTION' reason for change: Data Entry Error	Karol Moore (b) (4)	23 Oct 2020 19:06:16
	(b) (4)	
User opened query 'Per DM CLR: Please review AE and please update to specify the location/type of Congestion. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 05:49:45
User opened query 'DM-Coding: The verbatim CONGESTION cannot be referenced as reported. Please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding.' (Site from System).	Coder Import (b) (4)	24 Sep 2020 18:42:31
	(b) (4)	
Data point term sent to Coder	System	22 Sep 2020 13:10:31
User entered 'CONGESTION'	Monica Atwood (b) (4)	22 Sep 2020 13:10:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

US3312434

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '10 Sep 2020'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User entered empty.	System	22 Sep 2020 13:10:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '11 Sep 2020'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User entered empty.	System	22 Sep 2020 13:10:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	22 Sep 2020 13:10:30

US3312434

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

US3312434

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

US3312434

Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Not Related (NOT RELATED)'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

US3312434

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Not Related (NOT RELATED)'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

US3312434

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'None (NONE)'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'I'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

US3312434

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

US3312434

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

US3312434

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

US3312434

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:10:30

US3312434

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User entered '0'	System	22 Sep 2020 13:10:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18
User entered '0'	System	22 Sep 2020 13:10:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Runny nose - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 13:13:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 13:13:38
Data point term sent to Coder	System	22 Sep 2020 13:12:43
User entered 'RUNNY NOSE'	Monica Atwood (b) (4)	22 Sep 2020 13:12:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '10 Sep 2020'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User entered empty.	System	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '11 Sep 2020'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User entered empty.	System	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Not Related (NOT RELATED)'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Not Related (NOT RELATED)'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'None (NONE)'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'I'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) Monica Atwood (b) (4)	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User entered '0'	System	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24
User entered '0'	System	22 Sep 2020 13:12:08

US3312434

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:02:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User closed query 'Per DM CLR - RQ: Site's response noted as "CHANGE FROM BASELINE TO GRADE 3". Please confirm what is the grade of Hypertension at baseline? If it increases in grade, then the condition worsen. Please review and clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 06:07:19
Query 'Per DM CLR - RQ: Site's response noted as "CHANGE FROM BASELINE TO GRADE 3". Please confirm what is the grade of Hypertension at baseline? If it increases in grade, then the condition worsen. Please review and clarify.' answered with 'Per protocol-Grade 3 elevated blood pressure is AE' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 23:38:10
User opened query 'Per DM CLR - RQ: Site's response noted as "CHANGE FROM BASELINE TO GRADE 3". Please confirm what is the grade of Hypertension at baseline? If it increases in grade, then the condition worsen. Please review and clarify.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 11:00:13
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPERTENSION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:02:27
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPERTENSION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'CHANGE FROM BASELINE TO GRADE 3, AE PER PROTOCOL, NOT WORSENING OF CONDITION' (Site from DM).	Monica Atwood (b) (4) (b) (4)	17 Nov 2020 16:53:27

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPERTENSION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 09:37:34
User coded data point as SOC: Investigations, HLT: Cardiac and vascular investigations (excl enzyme tests), PT: Blood pressure systolic increased, LLT: Blood pressure systolic increased - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 23:42:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	17 Oct 2020 23:42:37
Data point term sent to Coder	System	17 Oct 2020 23:42:12
User entered 'elevated systolic blood pressure'	Karol Moore (b) (4)	17 Oct 2020 23:40:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '29 Sep 2020'	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '11:37'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User entered '29 Sep 2020 11:37'	System	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Monica Atwood (b) (4)	17 Nov 2020 17:00:20
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	17 Oct 2020 23:40:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '27 Oct 2020' reason for change: Data Entry Error	(b) (4)	17 Nov 2020 17:00:20
User entered empty.	Monica Atwood (b) (4)	17 Oct 2020 23:40:37
	(b) (4)	

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '11:17' reason for change: Data Entry Error	(b) (4)	17 Nov 2020 17:00:20
User entered empty.	Monica Atwood (b) (4)	17 Oct 2020 23:40:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User entered '27 Oct 2020 11:17'	System	17 Nov 2020 17:00:20
User entered empty.	System	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4)	17 Oct 2020 23:40:37
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:40:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #8 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 06:07:15
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #8 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' answered with 'no cm changes during AE timeframe' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 23:37:33
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #8 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 11:00:20
User entered 'I'	Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Monica Atwood (b) (4)	17 Nov 2020 17:00:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Karol Moore (b) (4)	17 Oct 2020 23:40:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User entered '0'	System	17 Oct 2020 23:40:37

US3312434

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30
User entered '0'	System	17 Oct 2020 23:40:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:02:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone disorders NEC, PT: Osteonecrosis, LLT: Avascular necrosis - version MedDRA\23.0.	Coder Import (b) (4)	24 Mar 2021 14:34:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Mar 2021 14:34:55
Data point term sent to Coder	System	23 Mar 2021 21:03:49
Coding entries removed.	(b) (4), (b) (6)	23 Mar 2021 21:03:49
User entered 'IDIOPATHIC AVASCULAR NECROSIS right hip' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 21:03:49
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone disorders NEC, PT: Osteonecrosis, LLT: Avascular necrosis - version MedDRA\23.0.	Coder Import (b) (4)	11 Jan 2021 21:32:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Jan 2021 21:32:43
Data point term sent to Coder	System	11 Jan 2021 21:07:15
User entered 'idiopathic avascular necrosis'	(b) (4), (b) (6)	11 Jan 2021 21:06:33

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User entered empty.	System	11 Jan 2021 21:06:33

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:40:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 21:06:33

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '01 Feb 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:40:19
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 21:06:33

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User entered empty.	System	11 Jan 2021 21:06:33

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:40:19
Data Entry Error		
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	11 Jan 2021 21:06:33

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:06:33

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User entered '0'	System	11 Jan 2021 21:06:33

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44
User entered 'I'	System	11 Jan 2021 21:06:33

US3312434

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:44

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:03:44
User entered 'USA-US300-2021-mRNA-1273-P301000017'	System	22 Feb 2021 16:02:19
User entered 'New'	(b) (4), (b) (6)	22 Feb 2021 16:02:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Mar 2021 16:19:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 16:19:09
User closed query 'Per DM CLR: Please confirm if this AE is a worsening of OSTEOARTHRITIS LEFT KNEE noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 11:19:39
User closed query 'Per DM CLR: Please note this AE#5 overlaps with AE#4. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 11:18:11
Data point term sent to Coder	System	23 Mar 2021 21:01:48
User closed query 'For coding purposes, please split SEVERE OSTEOARTHRITIS WITH AVASCULAR NECROSIS RIGHT HIP into separate entries.' (Site from System).	System	23 Mar 2021 21:01:20
Query 'For coding purposes, please split SEVERE OSTEOARTHRITIS WITH AVASCULAR NECROSIS RIGHT HIP into separate entries.' answered with 'UPdated' (Site from System).	(b) (4), (b) (6)	23 Mar 2021 21:01:20
Query 'Per DM CLR: Please confirm if this AE is a worsening of OSTEOARTHRITIS LEFT KNEE noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria.' answered with 'OA left knee is unrelated medical history item, this AE is referring to R Hip' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 21:01:12

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note this AE#5 overlaps with AE#4. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 21:00:48
Data point term sent to Coder	System	23 Mar 2021 20:48:21
User entered 'worsening OSTEOARTHRITIS RIGHT HIP' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 20:48:02
User opened query 'For coding purposes, please split SEVERE OSTEOARTHRITIS WITH AVASCULAR NECROSIS RIGHT HIP into separate entries.' (Site from System).	Coder Import (b) (4)	16 Mar 2021 18:26:53
User opened query 'Per DM CLR: Please confirm if this AE is a worsening of OSTEOARTHRITIS LEFT KNEE noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 05:57:26
User opened query 'Per DM CLR: Please note this AE#5 overlaps with AE#4. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 03:00:52
Data point term sent to Coder	System	24 Feb 2021 23:46:56
Coding entries removed.	(b) (4), (b) (6)	24 Feb 2021 23:46:20
User entered 'severe OSTEOARTHRITIS WITH AVASCULAR NECROSIS RIGHT HIP' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 23:46:20
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone disorders NEC, PT: Osteonecrosis, LLT: Avascular necrosis - version MedDRA\23.0.	Coder Import (b) (4)	24 Feb 2021 12:02:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Feb 2021 12:02:55
Data point term sent to Coder	System	19 Feb 2021 23:41:24
User entered 'end stage osteoarthritis with avascular necrosis right hip'	(b) (4), (b) (6)	19 Feb 2021 23:40:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:40:28

US3312434

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:40:28

US3312434

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:40:28

US3312434

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User closed query 'PV Query: (AE#1) Please confirm the onset date for the event end stage osteoarthritis with avascular necrosis right hip. Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious and the source narrative states the subject was diagnosed with idiopathic avascular necrosis on 15 Oct 2020.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:33:25
Query 'PV Query: (AE#1) Please confirm the onset date for the event end stage osteoarthritis with avascular necrosis right hip. Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious and the source narrative states the subject was diagnosed with idiopathic avascular necrosis on 15 Oct 2020.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 21:03:30
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	23 Mar 2021 21:03:23
User entered '15 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 21:03:23
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	23 Mar 2021 21:02:31
User entered '15 Oct 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 21:02:31
User opened query 'PV Query: (AE#1) Please confirm the onset date for the event end stage osteoarthritis with avascular necrosis right hip. Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious and the source narrative states the subject was diagnosed with idiopathic avascular necrosis on 15 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 15:16:29
User entered '01 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 23:40:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:40:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 23:40:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:40:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
	(b) (4)	
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	System	23 Mar 2021 21:03:23
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	23 Mar 2021 21:02:31
User entered '03 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 23:40:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:40:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 23:40:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:40:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:40:28

US3312434

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:40:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:40:28

US3312434

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:40:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User closed query 'PV Query: Please confirm the hospitalization dates. Admission date provided as both 01 Feb 2021 and 03 Feb 2021.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 11:52:41
Query 'PV Query: Please confirm the hospitalization dates. Admission date provided as both 01 Feb 2021 and 03 Feb 2021.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 21:08:16
User entered '01 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 21:07:59
User opened query 'PV Query: Please confirm the hospitalization dates. Admission date provided as both 01 Feb 2021 and 03 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 15:16:43
User entered '03 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 23:40:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User closed query 'PV Query: Please confirm discharge date. Narrative and Med record summary reports discharge as 03 Feb 2021 but EDC reports as 04 Feb 2021.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 11:52:44
Query 'PV Query: Please confirm discharge date. Narrative and Med record summary reports discharge as 03 Feb 2021 but EDC reports as 04 Feb 2021.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 21:08:20
User entered '03 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 21:07:59
User opened query 'PV Query: Please confirm discharge date. Narrative and Med record summary reports discharge as 03 Feb 2021 but EDC reports as 04 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 21:01:17
User entered '04 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 23:40:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:40:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:40:28

US3312434

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:40:28

US3312434

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:40:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:40:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:40:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:40:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User closed query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 11 Jan 2021, then event occurred).' (Site from Safety).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:33:39
Query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 11 Jan 2021, then event occurred).' answered with 'only applicable to Part A, subject received both Open Label vaccines' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 21:02:05
User opened query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 11 Jan 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 13:04:43
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	19 Feb 2021 23:40:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:40:28

US3312434

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:12:11
User entered '0'	(b) (4), (b) (6)	19 Feb 2021 23:40:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User closed query 'Per DM CLR: Treatment Required = 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). Query 'Per DM CLR: Treatment Required = 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 'present' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 12:54:10
User opened query 'Per DM CLR: Treatment Required = 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)	17 Mar 2021 22:37:34
User entered '1'	(b) (4), (b) (6)	08 Mar 2021 03:01:16
	(b) (4), (b) (6)	19 Feb 2021 23:40:28

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Folder: Adverse Events

Form: Adverse Events (5)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:40:28

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Folder: Adverse Events

Form: Adverse Events (5)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:40:28

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User closed query 'Per DM CLR: Narrative indicates that subject had " RIGHT TOTAL HIP REPLACEMENT." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 12:54:18
Query 'Per DM CLR: Narrative indicates that subject had " RIGHT TOTAL HIP REPLACEMENT." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'present' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 22:37:24
User opened query 'Per DM CLR: Narrative indicates that subject had " RIGHT TOTAL HIP REPLACEMENT." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 05:57:46
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]' canceled (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 16:12:30
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. [mRNA-1273 protocols where subject was hospitalization during study participation]' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 15:14:49

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PLEASE NOTE THAT THE SOURCE OF INFORMATION FOR THIS SAE REPORT IS THE SUBJECT'S VERBAL REPORT. SUBJECT, AT HER OPEN LABEL D29 VISIT, REPORTED RIGHT TOTAL HIP REPLACEMENT WITH POST-OPERATIVE HOSPITALIZATION DUE TO END STAGE OSTEOARTHRITIS WITH AVASCULAR NECROSIS OF RIGHT HIP. SUBJECT IS A 70 YEAR OLD FEMALE WITH H/O HTN, OSTEOPOROSIS AND OSTEOARTHRITIS AT SCREENING; SHE WAS LATER DIAGNOSED WITH IDIOPATHIC AVASCULAR NECROSIS OF THE RIGHT HIP ON 10/15/2020. THE OSTEOARTHRITIS WAS INITIALLY REPORTED TO INVOLVE THE LEFT KNEE BUT IS NOW BELIEVED THAT LEFT KNEE PAIN WAS RELATED TO RIGHT HIP OSTEOARTHRITIS WITH AVASCULAR NECROSIS. RIGHT TOTAL HIP REPLACEMENT TOOK PLACE ON 2/1/21 AND SHE WAS HOSPITALIZED POST-OPERATIVELY FROM 2/1/21—2/3/21. HER POST-OPERATIVE COURSE WAS COMPLICATED BY ANEMIA (HEMOGLOBIN DROPPED TO 8MG/DL RANGE) BUT SHE DID NOT REQUIRE TRANSFUSION. SHE REMAINED IN HOSPITAL FOR OBSERVATION AN EXTRA NIGHT FOR MONITORING OF ANEMIA. SHE WAS DISCHARGED ON PRN OXYCODONE (DOSE UNKNOWN) WHICH SHE TOOK FOR THE FIRST WEEK AND PRN TYLENOL 1000MG WHICH SHE STILL TAKES ON OCCASION BUT REPORTS TO BE RECOVERING NICELY AND IS ABOUT 80% BACK TO BASELINE. SHE WILL CONTINUE TO FOLLOW WITH HER ORTHOPEDIC SURGEON, NEXT FOLLOW-UP SCHEDULED 3/16/21.THIS IS AN SAE OF END STAGE OSTEOARTHRITIS WITH AVASCULAR NECROSIS OF THE RIGHT HIP JOINT REQUIRING HOSPITALIZATION FOR TOTAL HIP REPLACEMENT, NOT RELATED TO IP.	(b) (4), (b) (6)	24 Feb 2021 23:51:21

US3312434

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Narrative](#)

Audit	User	Time (GMT)
THIS IS ALSO AND SAE OF PROLONGED HOSPITALIZATION RELATED TO POST-OPERATIVE ANEMIA, NOT RELATED TO IP. MEDICAL RECORDS ARE BEING REQUESTED. Follow up 24Feb2021: email sent to Safety team as not enough characters to complete in EDC.' reason for change: Data Entry Error User entered 'Please note that the source of information for this SAE report is the subject's verbal report. Subject, at her open label D29 visit, reported right total hip replacement with post-operative hospitalization due to end stage osteoarthritis with avascular necrosis of right hip. Subject is a 70 year old female with h/o HTN, osteoporosis and osteoarthritis at screening; she was later diagnosed with idiopathic avascular necrosis of the right hip on 10/15/2020. The osteoarthritis was initially reported to involve the left knee but is now believed that left knee pain was related to right hip osteoarthritis with avascular necrosis. Right total hip replacement took place on 2/1/21 and she was hospitalized post-operatively from 2/1/21—2/3/21. Her post-operative course was complicated by anemia (hemoglobin dropped to 8mg/dL range) but she did not require transfusion. She remained in hospital for observation an extra night for monitoring of anemia. She was discharged on PRN oxycodone (dose unknown) which she took for the first week and PRN Tylenol 1000mg which she still takes on occasion but reports to be recovering nicely and is about 80% back to baseline. She will continue to follow with her orthopedic surgeon, next follow-up scheduled 3/16/21.This is an SAE of end stage osteoarthritis with avascular necrosis of the right hip joint requiring hospitalization for total hip replacement, not related to IP. This is also and SAE of prolonged hospitalization related to post-operative anemia, not related to IP. Medical records are being requested'		
	(b) (4), (b) (6)	19 Feb 2021 23:40:28

US3312434

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Feb 2021 23:40:28

US3312434

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Feb 2021 23:40:28

US3312434

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:02:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Feb 2021 23:40:28

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:07:45
User entered 'USA-US300-2021-mRNA-1273-P301000017'	(b) (4), (b) (6)	22 Feb 2021 16:07:36

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Anaemia postoperative, LLT: Anemia postoperative - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 18:28:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 18:28:00
Data point term sent to Coder	System	19 Feb 2021 23:42:25
User entered 'Post operative anemia'	(b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User closed query 'PV Query: Please confirm if the onset date of post-operative anemia should be 02-Feb-2021 when the drop in the hemoglobin (7.7 mg/dL)was noticed' (Site from Safety).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 11:53:33
Query 'PV Query: Please confirm if the onset date of post-operative anemia should be 02-Feb-2021 when the drop in the hemoglobin (7.7 mg/dL)was noticed' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 22:36:37
User entered '02 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 22:36:27
User opened query 'PV Query: Please confirm if the onset date of post-operative anemia should be 02-Feb-2021 when the drop in the hemoglobin (7.7 mg/dL)was noticed' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 21:02:06
User entered '01 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:47:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User closed query 'PV Query: Please confirm if the date of resolution for post-operative anemia should be 03-Feb-2021 when the hemoglobin had improved to 8 mg/dL.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 11:53:46
Query 'PV Query: Please confirm if the date of resolution for post-operative anemia should be 03-Feb-2021 when the hemoglobin had improved to 8 mg/dL.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 22:36:09
User entered '03 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 22:36:02
User opened query 'PV Query: Please confirm if the date of resolution for post-operative anemia should be 03-Feb-2021 when the hemoglobin had improved to 8 mg/dL.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 21:02:26
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	24 Feb 2021 23:48:14
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	24 Feb 2021 23:48:14
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	24 Feb 2021 23:47:56
User entered '02 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 23:47:56
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

Death

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User closed query 'PV Query: Please confirm the hospitalization dates. Admission date provided as both 01 Feb 2021 and 03 Feb 2021.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 11:53:58
Query 'PV Query: Please confirm the hospitalization dates. Admission date provided as both 01 Feb 2021 and 03 Feb 2021.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 22:34:22
User entered '01 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 22:34:16
User opened query 'PV Query: Please confirm the hospitalization dates. Admission date provided as both 01 Feb 2021 and 03 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 15:21:18
User entered '03 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User closed query 'PV Query: Please confirm discharge date. Narrative and Med record summary reports discharge as 03 Feb 2021 but EDC reports as 04 Feb 2021.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 11:54:12
Query 'PV Query: Please confirm discharge date. Narrative and Med record summary reports discharge as 03 Feb 2021 but EDC reports as 04 Feb 2021.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 22:34:27
User entered '03 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 22:34:16
User opened query 'PV Query: Please confirm discharge date. Narrative and Med record summary reports discharge as 03 Feb 2021 but EDC reports as 04 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 21:01:34
User entered '04 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User closed query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 11 Jan 2021, then event occurred).' (Site from Safety).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:34:16
Query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 11 Jan 2021, then event occurred).' answered with 'NA-subject received both OL doses' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 21:04:13
User opened query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 11 Jan 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 13:06:27
Query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on [date], then event occurred).' canceled (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 16:10:36
User opened query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on [date], then event occurred).' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 15:20:07
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

None

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 12:56:24
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' answered with 'no cm given, subject stayed an extra night for observation' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 22:35:31
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 03:02:12
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Feb 2021 23:42:24
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 23:42:24
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Feb 2021 23:42:02
User entered '0'	(b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
Query 'PV Query: (AE#2) Please provide treatment given for the event postoperative anemia 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.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:12:10
User opened query 'PV Query: (AE#2) Please provide treatment given for the event postoperative anemia including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 15:20:40
User entered '0'	(b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:48:14
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	06 Apr 2021 02:32:59

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PLEASE NOTE THAT THE SOURCE OF INFORMATION FOR THIS SAE REPORT IS THE SUBJECT'S VERBAL REPORT. SUBJECT, AT HER OPEN LABEL D29 VISIT, REPORTED RIGHT TOTAL HIP REPLACEMENT WITH POST-OPERATIVE HOSPITALIZATION DUE TO END STAGE OSTEOARTHRITIS WITH AVASCULAR NECROSIS OF RIGHT HIP. SUBJECT IS A 70 YEAR OLD FEMALE WITH H/O HTN, OSTEOPOROSIS AND OSTEOARTHRITIS AT SCREENING; SHE WAS LATER DIAGNOSED WITH IDIOPATHIC AVASCULAR NECROSIS OF THE RIGHT HIP ON 10/15/2020. THE OSTEOARTHRITIS WAS INITIALLY REPORTED TO INVOLVE THE LEFT KNEE BUT IS NOW BELIEVED THAT LEFT KNEE PAIN WAS RELATED TO RIGHT HIP OSTEOARTHRITIS WITH AVASCULAR NECROSIS. RIGHT TOTAL HIP REPLACEMENT TOOK PLACE ON 2/1/21 AND SHE WAS HOSPITALIZED POST-OPERATIVELY FROM 2/1/21—2/3/21. HER POST-OPERATIVE COURSE WAS COMPLICATED BY ANEMIA (HEMOGLOBIN DROPPED TO 8MG/DL RANGE) BUT SHE DID NOT REQUIRE TRANSFUSION. SHE REMAINED IN HOSPITAL FOR OBSERVATION AN EXTRA NIGHT FOR MONITORING OF ANEMIA. SHE WAS DISCHARGED ON PRN OXYCODONE (DOSE UNKNOWN) WHICH SHE TOOK FOR THE FIRST WEEK AND PRN TYLENOL 1000MG WHICH SHE STILL TAKES ON OCCASION BUT REPORTS TO BE RECOVERING NICELY AND IS ABOUT 80% BACK TO BASELINE. SHE WILL CONTINUE TO FOLLOW WITH HER ORTHOPEDIC SURGEON, NEXT FOLLOW-UP SCHEDULED 3/16/21.THIS IS AN SAE OF END STAGE OSTEOARTHRITIS WITH AVASCULAR NECROSIS OF THE RIGHT HIP JOINT REQUIRING HOSPITALIZATION FOR TOTAL HIP REPLACEMENT, NOT RELATED TO IP.	(b) (4), (b) (6)	24 Feb 2021 23:50:20

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Narrative](#)

Audit	User	Time (GMT)
THIS IS ALSO AND SAE OF PROLONGED HOSPITALIZATION RELATED TO POST-OPERATIVE ANEMIA, NOT RELATED TO IP. MEDICAL RECORDS ARE BEING REQUESTED.FOLLOW UP 24FEB2021: Sent via email to Safety team as not enough characters to complete in EDC field.' reason for change: Data Entry Error		

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PLEASE NOTE THAT THE SOURCE OF INFORMATION FOR THIS SAE REPORT IS THE SUBJECT'S VERBAL REPORT. SUBJECT, AT HER OPEN LABEL D29 VISIT, REPORTED RIGHT TOTAL HIP REPLACEMENT WITH POST-OPERATIVE HOSPITALIZATION DUE TO END STAGE OSTEOARTHRITIS WITH AVASCULAR NECROSIS OF RIGHT HIP. SUBJECT IS A 70 YEAR OLD FEMALE WITH H/O HTN, OSTEOPOROSIS AND OSTEOARTHRITIS AT SCREENING; SHE WAS LATER DIAGNOSED WITH IDIOPATHIC AVASCULAR NECROSIS OF THE RIGHT HIP ON 10/15/2020. THE OSTEOARTHRITIS WAS INITIALLY REPORTED TO INVOLVE THE LEFT KNEE BUT IS NOW BELIEVED THAT LEFT KNEE PAIN WAS RELATED TO RIGHT HIP OSTEOARTHRITIS WITH AVASCULAR NECROSIS. RIGHT TOTAL HIP REPLACEMENT TOOK PLACE ON 2/1/21 AND SHE WAS HOSPITALIZED POST-OPERATIVELY FROM 2/1/21—2/3/21. HER POST-OPERATIVE COURSE WAS COMPLICATED BY ANEMIA (HEMOGLOBIN DROPPED TO 8MG/DL RANGE) BUT SHE DID NOT REQUIRE TRANSFUSION. SHE REMAINED IN HOSPITAL FOR OBSERVATION AN EXTRA NIGHT FOR MONITORING OF ANEMIA. SHE WAS DISCHARGED ON PRN OXYCODONE (DOSE UNKNOWN) WHICH SHE TOOK FOR THE FIRST WEEK AND PRN TYLENOL 1000MG WHICH SHE STILL TAKES ON OCCASION BUT REPORTS TO BE RECOVERING NICELY AND IS ABOUT 80% BACK TO BASELINE. SHE WILL CONTINUE TO FOLLOW WITH HER ORTHOPEDIC SURGEON, NEXT FOLLOW-UP SCHEDULED 3/16/21.THIS IS AN SAE OF END STAGE OSTEOARTHRITIS WITH AVASCULAR NECROSIS OF THE RIGHT HIP JOINT REQUIRING HOSPITALIZATION FOR TOTAL HIP REPLACEMENT, NOT RELATED TO IP.	(b) (4), (b) (6)	24 Feb 2021 23:49:14

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Narrative](#)

Audit	User	Time (GMT)
THIS IS ALSO AND SAE OF PROLONGED HOSPITALIZATION RELATED TO POST-OPERATIVE ANEMIA, NOT RELATED TO IP. MEDICAL RECORDS ARE BEING REQUESTED.Follow up 24Feb2021: continued'		
reason for change: Data Entry Error User entered 'Please note that the source of information for this SAE report is the subject's verbal report. Subject, at her open label D29 visit, reported right total hip replacement with post-operative hospitalization due to end stage osteoarthritis with avascular necrosis of right hip. Subject is a 70 year old female with h/o HTN, osteoporosis and osteoarthritis at screening; she was later diagnosed with idiopathic avascular necrosis of the right hip on 10/15/2020. The osteoarthritis was initially reported to involve the left knee but is now believed that left knee pain was related to right hip osteoarthritis with avascular necrosis. Right total hip replacement took place on 2/1/21 and she was hospitalized post-operatively from 2/1/21—2/3/21. Her post-operative course was complicated by anemia (hemoglobin dropped to 8mg/dL range) but she did not require transfusion. She remained in hospital for observation an extra night for monitoring of anemia. She was discharged on PRN oxycodone (dose unknown) which she took for the first week and PRN Tylenol 1000mg which she still takes on occasion but reports to be recovering nicely and is about 80% back to baseline. She will continue to follow with her orthopedic surgeon, next follow-up scheduled 3/16/21.This is an SAE of end stage osteoarthritis with avascular necrosis of the right hip joint requiring hospitalization for total hip replacement, not related to IP. This is also and SAE of prolonged hospitalization related to post-operative anemia, not related to IP. Medical records are being requested'	(b) (4), (b) (6)	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:02:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Feb 2021 23:42:02

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Postoperative pain - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 19:55:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 19:55:47
Data point term sent to Coder	System	07 Apr 2021 19:55:10
User entered 'POST OPERATIVE PAIN'	Karol Moore (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered '01 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User entered empty.	System	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered '07 Mar 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User entered empty.	System	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered 'No (N)'	(b) (4)	07 Apr 2021 19:54:24
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered '0'	(b) (4) Karol Moore (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered empty.	(b) (4) Karol Moore (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered empty.	(b) (4) Karol Moore (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered empty.	(b) (4) Karol Moore (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	07 Apr 2021 19:54:24
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered empty.	(b) (4) Karol Moore (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered empty.	(b) (4) Karol Moore (b) (4)	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

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Generated On: 09 Jun 2021 17:02:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User entered '0'	System	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46
User entered 'I'	System	07 Apr 2021 19:54:24

US3312434

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:02:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:46

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension exacerbated - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 19:56:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 19:56:35
Data point term sent to Coder	System	07 Apr 2021 19:56:12
User entered 'EXACERBATION OF HYPERTENSION'	Karol Moore (b) (4)	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered 'Yes (Y)'	(b) (4)	07 Apr 2021 19:55:37
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	08 Apr 2021 19:22:14
User entered '11 Nov 2020' reason for change: Data Entry Error	System	08 Apr 2021 19:22:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Karol Moore (b) (4)	08 Apr 2021 19:22:14
User entered 'UN Nov 2020' (non-conformant).	(b) (4)	07 Apr 2021 19:55:37
	System	07 Apr 2021 19:55:37
	Karol Moore (b) (4)	07 Apr 2021 19:55:37
	(b) (4)	

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User entered empty.	System	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered '03 Feb 2021'	(b) (4)	07 Apr 2021 19:55:37
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered empty.	(b) (4)	07 Apr 2021 19:55:37
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User entered empty.	System	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	07 Apr 2021 19:55:37
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered 'No (N)'	(b) (4)	07 Apr 2021 19:55:37
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered '0'	(b) (4) Karol Moore (b) (4)	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered empty.	(b) (4)	07 Apr 2021 19:55:37
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered empty.	(b) (4)	07 Apr 2021 19:55:37
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered empty.	(b) (4) Karol Moore (b) (4)	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	07 Apr 2021 19:55:37
	Karol Moore (b) (4)	
	(b) (4)	

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:59:27
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User entered '0'	System	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56
User entered 'I'	System	07 Apr 2021 19:55:37

US3312434

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:02:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:53:56

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:02:25

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:26:04
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:00

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:25

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
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.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:32:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:32:57
Data point term sent to Coder User entered 'lisinopril'	System Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:21 24 Sep 2020 16:31:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'hypertension'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '10'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'un UNK 2018'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '0'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 16:31:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 16:31:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Sep 2020 16:31:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: BISPHOSPHONATES, PRODUCT: ALENDRONATE SODIUM, PRODUCTSYNONYM: ALENDRONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:32:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:32:57
Data point term sent to Coder User entered 'alendronate'	System Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:22 24 Sep 2020 16:31:54

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:54

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'osteoporosis'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:54

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '35'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:54

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:54

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:54

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'every week (QS)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:54

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:54

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:54

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:54

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'un UNK 2018'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:54

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '0'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:54

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:54

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:54

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:31:54

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 16:31:54

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 16:31:54

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	24 Sep 2020 16:31:54

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:33:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:33:01
Data point term sent to Coder	System	24 Sep 2020 16:32:22
User entered 'multivitamin'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:16

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:16

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'health maintenance'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:16

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'I'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:16

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'tablet (TABLET)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:16

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:16

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:16

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:16

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:16

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:16

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'un UNK 2017'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:16

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '0'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:16

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:16

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:16

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:16

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 16:32:16

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 16:32:16

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Sep 2020 16:32:16

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:33:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:33:51
Data point term sent to Coder	System	24 Sep 2020 16:33:25
User entered 'calcium'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'health maintenance'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '500'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'un UNK 2018'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '0'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:32:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 16:32:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 16:32:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Sep 2020 16:32:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:25

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:33:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:33:53
Data point term sent to Coder User entered 'vitamin d3'	System Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:25 24 Sep 2020 16:33:11

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:11

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'health maintenance'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:11

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '2000'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:11

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 12:13:33
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate. ' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	26 Oct 2020 23:39:09
User entered 'ug (ug)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	26 Oct 2020 23:39:05
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 05:41:15
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:11

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:11

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:11

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:25

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:11

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:11

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:11

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '15 Jun 2020'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:11

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '0'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:11

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:11

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:11

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:11

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 16:33:11

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 16:33:11

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Sep 2020 16:33:11

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:34:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:34:49
Data point term sent to Coder	System	24 Sep 2020 16:34:29
User entered 'acetaminophen'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:51

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:51

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'osteoarthritis left knee'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:51

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '1000'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:51

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:51

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:51

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:51

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:51

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:51

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:51

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '26 Jun 2020'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:51

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '0'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:51

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:51

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:51

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:33:51

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 16:33:51

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 16:33:51

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 16:33:51

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:34:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:34:49
Data point term sent to Coder User entered 'naproxen'	System Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:34:31 24 Sep 2020 16:34:18

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:34:18

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'osteoarthritis left knee'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:34:18

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '440'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:34:18

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:34:18

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:34:18

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:34:18

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:34:18

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:34:18

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:34:18

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '26 Jun 2020'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:34:18

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '0'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:34:18

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:34:18

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:34:18

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	24 Sep 2020 16:34:18

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 16:34:18

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 16:34:18

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 16:34:18

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:25

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
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.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:45:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:45:25
Data point term sent to Coder	System	29 Oct 2020 13:13:44
User entered 'Lisinopril'	(b) (4), (b) (6)	29 Oct 2020 13:13:06

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 13:13:06

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'hypertension'	(b) (4), (b) (6)	29 Oct 2020 13:13:06

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '20'	(b) (4), (b) (6)	29 Oct 2020 13:13:06

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Oct 2020 13:13:06

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 13:13:06

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'once daily (QD)'	(b) (4), (b) (6)	29 Oct 2020 13:13:06

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 13:13:06

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Oct 2020 13:13:06

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 13:13:06

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '20 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 13:13:06

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 13:13:06

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 13:13:06

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 13:13:06

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 13:13:06

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 13:13:06

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 13:13:06

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 13:13:06

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
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) (b) (4)	30 Oct 2020 03:45:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:45:58
Data point term sent to Coder	System	29 Oct 2020 13:14:47
User entered 'SEASONAL INFLUENZA VACCINE'	(b) (4), (b) (6)	29 Oct 2020 13:14:23

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 13:14:23

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'SEASONAL INFLUENZA VACCINE'	(b) (4), (b) (6)	29 Oct 2020 13:14:23

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'l'	(b) (4), (b) (6)	29 Oct 2020 13:14:23

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Other (OTHER)'	(b) (4), (b) (6)	29 Oct 2020 13:14:23

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'INJECTION'	(b) (4), (b) (6)	29 Oct 2020 13:14:23

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'once (ONCE)'	(b) (4), (b) (6)	29 Oct 2020 13:14:23

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 13:14:23

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	29 Oct 2020 13:14:23

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 13:14:23

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '16 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 13:14:23

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 13:14:23

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 13:14:23

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '16 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 13:14:23

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 13:14:23

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:38
User entered empty.	System	29 Oct 2020 13:14:23

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:38
User entered empty.	System	29 Oct 2020 13:14:23

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:38
User entered empty.	System	29 Oct 2020 13:14:23

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:55:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:55:28
Data point term sent to Coder User entered 'Amlodipine'	System Kelly Moen (b) (4) (b) (4)	24 Nov 2020 20:54:22 24 Nov 2020 20:53:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	24 Nov 2020 20:53:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening hypertension should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 16:06:01
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening hypertension should be recorded, and update con med indication or provide clarification. ' answered with 'NOT CONSIDERED AN AE. PER SUBJECT IS CONSIDERED STABLE.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 18:07:11
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening hypertension should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 18:07:04
User entered 'hypertension'	Kelly Moen (b) (4) (b) (4)	24 Nov 2020 20:53:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '5'	Kelly Moen (b) (4) (b) (4)	24 Nov 2020 20:53:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'mg (mg)'	Kelly Moen (b) (4) (b) (4)	24 Nov 2020 20:53:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Kelly Moen (b) (4) (b) (4)	24 Nov 2020 20:53:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'once daily (QD)'	Kelly Moen (b) (4) (b) (4)	24 Nov 2020 20:53:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Kelly Moen (b) (4) (b) (4)	24 Nov 2020 20:53:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Oral (ORAL)'	Kelly Moen (b) (4) (b) (4)	24 Nov 2020 20:53:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Kelly Moen (b) (4) (b) (4)	24 Nov 2020 20:53:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '22 Nov 2020'	Kelly Moen (b) (4) (b) (4)	24 Nov 2020 20:53:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '0'	Kelly Moen (b) (4) (b) (4)	24 Nov 2020 20:53:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	24 Nov 2020 20:53:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	Kelly Moen (b) (4) (b) (4)	24 Nov 2020 20:53:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	24 Nov 2020 20:53:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 20:53:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 20:53:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 20:53:38

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:35:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:35:38
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	07 Apr 2021 20:21:04
Data point term sent to Coder	System	07 Apr 2021 19:43:51
Coding entries removed.	Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:43:42
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:18:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 12:09:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 12:09:38
Data point term sent to Coder	System	15 Mar 2021 18:09:13
Coding entries removed.	(b) (4), (b) (6)	15 Mar 2021 18:09:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 16:40:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 16:40:54
Data point term sent to Coder	System	25 Feb 2021 16:40:10
User entered 'oxycodone'	(b) (4), (b) (6)	25 Feb 2021 16:39:40

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 16:39:40

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Un-verified.	(b) (4) Karol Moore (b) (4)	07 Apr 2021 19:43:42
User entered 'POST-OP PAIN (RIGHT HIP REPLACEMENT)' reason for change: Data Entry Error	(b) (4) Karol Moore (b) (4)	07 Apr 2021 19:43:42
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:18:14
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the type of surgery. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 16:06:09
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the type of surgery. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'UPDATED.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 18:09:14
User entered 'OSTEOARTHRITIS IN RIGHT HIP' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 18:09:08
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the type of surgery. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 03:43:01
User entered 'Right hip replacement'	(b) (4), (b) (6)	25 Feb 2021 16:39:40

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '5'	(b) (4), (b) (6)	25 Feb 2021 16:39:40

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Feb 2021 16:39:40

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 16:39:40

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'as needed (PRN)'	(b) (4), (b) (6)	25 Feb 2021 16:39:40

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 16:39:40

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 16:39:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 16:39:48
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 16:39:48
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 16:39:40
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 16:39:40

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 16:39:40

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '03 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 16:39:40

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 16:39:40

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 16:39:40

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:42
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:40:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
Query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'CORRECT AS ENTERED. AE CHANGED' (Site from DM).	(b) (4) Karol Moore (b) (4)	07 Apr 2021 19:44:19
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:12:33
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '10 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 16:39:40

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 16:39:40

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:42
User entered empty.	System	25 Feb 2021 16:39:40

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:42
User entered empty.	System	25 Feb 2021 16:39:40

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:42
User entered empty.	System	25 Feb 2021 16:39:40

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:25

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 16:45:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 16:45:54
Data point term sent to Coder	System	25 Feb 2021 16:45:20
User entered 'aspirin'	(b) (4), (b) (6)	25 Feb 2021 16:44:29

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 16:44:29

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Deep vein thrombosis prophylaxis'	(b) (4), (b) (6)	25 Feb 2021 16:44:29

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '325'	(b) (4), (b) (6)	25 Feb 2021 16:44:29

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Feb 2021 16:44:29

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 16:44:29

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Feb 2021 16:44:29

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 16:44:29

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Feb 2021 16:44:29

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 16:44:29

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '04 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 16:44:29

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 16:44:29

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 16:44:29

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 16:44:29

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 16:44:29

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 16:44:29

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 16:44:29

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Feb 2021 16:44:29

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:46
User closed query 'Per DM CLR: this Con Med was added/ had dose increased on UN NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:41:01
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
Query 'Per DM CLR: this Con Med was added/ had dose increased on UN NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'UPDATED AE AND INDICATION' (Site from DM).	(b) (4) Karol Moore (b) (4)	07 Apr 2021 19:45:49
User opened query 'Per DM CLR: this Con Med was added/ had dose increased on UN NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:12:50
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:18:14
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Feb 2021 16:47:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Feb 2021 16:47:55
Data point term sent to Coder	System	25 Feb 2021 16:47:21
User entered 'Hydrochlorothiazide'	(b) (4), (b) (6)	25 Feb 2021 16:46:31

PRODUCTION RELEASE (v12.003
EAB) (1725)

2373 of 2612

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 16:46:31

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'hypertension'	(b) (4), (b) (6)	25 Feb 2021 16:46:31

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:46
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:41:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'CORRECT AS ENTERED. CONFIRMED ON MEDICAL RELEASE FORMS' (Site from DM).	(b) (4)	
	Karol Moore (b) (4)	07 Apr 2021 19:46:24
	(b) (4)	
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:13:02
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '12.5'	(b) (4), (b) (6)	25 Feb 2021 16:46:31

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 16:06:16
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate. ' answered with 'UPDATED.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 18:11:15
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 18:11:02
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 03:43:31
User entered 'mL (mL)'	(b) (4), (b) (6)	25 Feb 2021 16:46:31

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 16:46:31

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Feb 2021 16:46:31

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 16:46:31

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Feb 2021 16:46:31

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 16:46:31

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'un Nov 2020'	(b) (4), (b) (6)	25 Feb 2021 16:46:31

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 16:46:31

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 16:46:31

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '03 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 16:46:31

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:46
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 16:46:31

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:46
User entered '1'	System	25 Feb 2021 16:46:31

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:46
User entered '1'	System	25 Feb 2021 16:46:31

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:46
User entered '804 (804)'	System	25 Feb 2021 16:46:31

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 13:16:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	31 Mar 2021 13:16:30
Data point term sent to Coder	System	23 Mar 2021 21:31:40
Coding entries removed.	(b) (4), (b) (6)	23 Mar 2021 21:31:24
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:18:14
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 07:45:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	08 Mar 2021 07:45:07
Data point term sent to Coder	System	25 Feb 2021 16:50:23
User entered 'Meloxicam'	(b) (4), (b) (6)	25 Feb 2021 16:49:52

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 16:49:52

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:31:24
User entered 'Worsening Osteoarthritis Right hip' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 21:31:24
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:18:14
User closed query 'Per DM CLR: The corresponding recorded AE does not show 'ConMed Administered' for Action Taken. Please update Action Taken for AE as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 16:06:22
Query 'Per DM CLR: The corresponding recorded AE does not show 'ConMed Administered' for Action Taken. Please update Action Taken for AE as appropriate. ' answered with 'UPDATED.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 18:12:31
User opened query 'Per DM CLR: The corresponding recorded AE does not show 'ConMed Administered' for Action Taken. Please update Action Taken for AE as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 03:44:48
User entered 'severe osteoarthritis Avascular Necrosis right hip'	(b) (4), (b) (6)	25 Feb 2021 16:49:52

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '7.5'	(b) (4), (b) (6)	25 Feb 2021 16:49:52

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Feb 2021 16:49:52

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 16:49:52

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Feb 2021 16:49:52

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 16:49:52

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Feb 2021 16:49:52

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 16:49:52

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:25

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '02 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 16:49:52

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 16:49:52

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 16:49:52

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '16 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 16:49:52

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 16:49:52

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:49
User entered '1'	System	25 Feb 2021 16:49:52

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:49
User entered '1'	System	25 Feb 2021 16:49:52

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:49
User entered '804 (804)'	System	25 Feb 2021 16:49:52

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:53
User closed query 'Per DM CLR: Please note, the medication cannot be verified as entered. Please update the Medication Name to reflect the complete name (either trade or generic) of the medication. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 15:53:38
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
Query 'Per DM CLR: Please note, the medication cannot be verified as entered. Please update the Medication Name to reflect the complete name (either trade or generic) of the medication. Update eCRF as appropriate. ' answered with 'GENERIC/TRADE NAME UNKNOWN. MEDICAL RECORDS DID NOT SPECIFY' (Site from DM).	(b) (4)	
	Karol Moore (b) (4)	07 Apr 2021 19:48:04
	(b) (4)	
User opened query 'Per DM CLR: Please note, the medication cannot be verified as entered. Please update the Medication Name to reflect the complete name (either trade or generic) of the medication. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 16:25:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, PRODUCT: ANESTHETICS, LOCAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 10:42:38
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 10:42:38
	(b) (4)	
Data point term sent to Coder	System	23 Mar 2021 21:32:41
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:18:14
Data point term sent to Coder	System	11 Mar 2021 17:09:01
User entered 'spinal anesthesia'	(b) (4), (b) (6)	11 Mar 2021 17:08:36

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 17:08:36

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:32:30
User entered 'Worsening Osteoarthritis Right hip' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 21:32:30
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'severe osteoarthritis Avascular Necrosis'	(b) (4), (b) (6)	11 Mar 2021 17:08:36

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'unk'	(b) (4), (b) (6)	11 Mar 2021 17:08:36

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Other (OTHER)'	(b) (4), (b) (6)	11 Mar 2021 17:08:36

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'unk'	(b) (4), (b) (6)	11 Mar 2021 17:08:36

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'once (ONCE)'	(b) (4), (b) (6)	11 Mar 2021 17:08:36

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:08:36

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Other (OTHER)'	(b) (4), (b) (6)	11 Mar 2021 17:08:36

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'intrathecal'	(b) (4), (b) (6)	11 Mar 2021 17:08:36

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '01 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 17:08:36

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 17:08:36

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 17:08:36

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '01 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 17:08:36

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 17:08:36

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:53
User entered empty.	System	11 Mar 2021 17:08:36

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:53
User entered empty.	System	11 Mar 2021 17:08:36

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:53
User entered empty.	System	11 Mar 2021 17:08:36

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, PRODUCT: I.V. SOLUTIONS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 12:31:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 12:31:27
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	09 Apr 2021 15:59:27
Data point term sent to Coder	System	09 Apr 2021 14:32:34
User closed query 'CDM Coding : Per query response, please update the drug name as INTRAVENOUS FLUIDS (UNKNOWN) in the drug name field. Please make changes appropriately. Thank you.' (Site from System).	System	09 Apr 2021 14:32:06
Query 'CDM Coding : Per query response, please update the drug name as INTRAVENOUS FLUIDS (UNKNOWN) in the drug name field. Please make changes appropriately. Thank you.' answered with 'UPDATED PER QUERY RESOLUTION' (Site from System).	Karol Moore (b) (4) (b) (4)	09 Apr 2021 14:32:06
DataPoint Un-verified.	Karol Moore (b) (4) (b) (4)	09 Apr 2021 14:31:31
Signature has been broken.	Karol Moore (b) (4) (b) (4)	09 Apr 2021 14:31:31
User entered 'INTRAVENOUS FLUIDS (UNKNOWN)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	09 Apr 2021 14:31:31
User opened query 'CDM Coding : Per query response, please update the drug name as INTRAVENOUS FLUIDS (UNKNOWN) in the drug name field. Please make changes appropriately. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	09 Apr 2021 11:38:34
Data point term sent to Coder	System	08 Apr 2021 19:25:39
User closed query 'CDM Coding : Please provide the specific trade name for the reported medication INTRAVENOUS FLUIDS and update the response in the drug name field along with active ingredients. Thank you.	System	08 Apr 2021 19:25:08

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 17:02:25
[Name of Medication](#)

Audit	User	Time (GMT)
' (Site from System).		
Query 'CDM Coding : Please provide the specific trade name for the reported medication INTRAVENOUS FLUIDS and update the response in the drug name field along with active ingredients. Thank you.	Karol Moore (b) (4)	08 Apr 2021 19:25:08
' answered with 'COMPLETE TRADE/GENERIC NAME UNKNOWN. MEDICAL RECORDS DID NOT SPECIFY' (Site from System).		
User opened query 'CDM Coding : Please provide the specific trade name for the reported medication INTRAVENOUS FLUIDS and update the response in the drug name field along with active ingredients. Thank you.	Coder Import (b) (4)	08 Apr 2021 06:53:41
' (Site from System).		
User closed query 'Per DM CLR: Please note, the medication cannot be verified as entered. Please update the Medication Name to reflect the complete name (either trade or generic) of the medication. Update eCRF as appropriate.	(b) (4), (b) (6)	08 Apr 2021 06:42:14
' (Site from DM).		
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
Query 'Per DM CLR: Please note, the medication cannot be verified as entered. Please update the Medication Name to reflect the complete name (either trade or generic) of the medication. Update eCRF as appropriate.	Karol Moore (b) (4)	07 Apr 2021 19:49:37
' answered with 'CORRECT AS ENTERED. COMPLETE TRADE/GENERIC NAME UNKNOWN. MEDICAL RECORDS DID NOT SPECIFY' (Site from DM).		
User opened query 'Per DM CLR: Please note, the medication cannot be verified as entered. Please update the Medication Name to reflect the complete name (either trade or generic) of the medication. Update eCRF as appropriate.	(b) (4), (b) (6)	05 Apr 2021 16:25:16
' (Site from DM).		
Data point term sent to Coder	System	23 Mar 2021 21:32:43
Coding entries removed.	(b) (4), (b) (6)	23 Mar 2021 21:32:41

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:25

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:18:14
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, PRODUCT: I.V. SOLUTIONS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:08:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:08:46
Data point term sent to Coder	System	11 Mar 2021 17:23:13
User entered 'intravenous fluids'	(b) (4), (b) (6)	11 Mar 2021 17:22:17

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 17:22:17

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:32:41
User entered 'Worsening Osteoarthritis Right hip' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 21:32:41
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'severe osteoarthritis Avascular Necrosis'	(b) (4), (b) (6)	11 Mar 2021 17:22:17

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'unk'	(b) (4), (b) (6)	11 Mar 2021 17:22:17

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'mL (mL)'	(b) (4), (b) (6)	11 Mar 2021 17:22:17

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:22:17

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'as needed (PRN)'	(b) (4), (b) (6)	11 Mar 2021 17:22:17

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:22:17

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4), (b) (6)	11 Mar 2021 17:22:17

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:22:17

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '01 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 17:22:17

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 17:22:17

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 17:22:17

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '02 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 17:22:17

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 17:22:17

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:58
User entered empty.	System	11 Mar 2021 17:22:17

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:58
User entered empty.	System	11 Mar 2021 17:22:17

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:53:58
User entered empty.	System	11 Mar 2021 17:22:17

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:01
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 13:26:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 13:26:23
Data point term sent to Coder	System	23 Mar 2021 21:33:45
Coding entries removed.	(b) (4), (b) (6)	23 Mar 2021 21:32:53
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:18:14
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 13:54:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 13:54:43
Data point term sent to Coder	System	11 Mar 2021 17:24:16
User entered 'lovenox'	(b) (4), (b) (6)	11 Mar 2021 17:23:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:01
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 17:23:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:01
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:32:53
User entered 'Worsening Osteoarthritis Right hip' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 21:32:53
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'severe osteoarthritis Avascular Necrosis'	(b) (4), (b) (6)	11 Mar 2021 17:23:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:01
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'unk'	(b) (4), (b) (6)	11 Mar 2021 17:23:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:01
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Mar 2021 17:23:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:01
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:23:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:01
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Mar 2021 17:23:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:01
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:23:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:01
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	11 Mar 2021 17:23:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:01
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:23:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:01
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '01 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 17:23:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:01
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 17:23:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:01
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 17:23:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:01
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '02 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 17:23:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:01
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 17:23:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:01
User entered '1'	System	11 Mar 2021 17:23:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:01
User entered '1'	System	11 Mar 2021 17:23:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:01
User entered '804 (804)'	System	11 Mar 2021 17:23:21

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, # 16 / (Start date 02 FEB 2021-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 11:13:50
' (Site from DM).		
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, # 16 / (Start date 02 FEB 2021- ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	25 Mar 2021 23:26:56
' answered with 'CM 15 inactivated' (Site from DM).		
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 21:37:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 21:37:41
Data point term sent to Coder	System	23 Mar 2021 21:06:53
Coding entries removed.	(b) (4), (b) (6)	23 Mar 2021 21:06:09
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, # 16 / (Start date 02 FEB 2021-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	21 Mar 2021 01:01:17
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:18:14

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:25

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Mar 2021 17:25:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Mar 2021 17:25:55
Data point term sent to Coder	System	11 Mar 2021 17:25:16
User entered 'acetaminophen'	(b) (4), (b) (6)	11 Mar 2021 17:24:39

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 17:24:39

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:06:09
User entered 'worsening OSTEOARTHRITIS Right hip' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 21:06:09
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'severe osteoarthritis Avascular Necrosis'	(b) (4), (b) (6)	11 Mar 2021 17:24:39

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '1000'	(b) (4), (b) (6)	11 Mar 2021 17:24:39

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Mar 2021 17:24:39

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:24:39

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'as needed (PRN)'	(b) (4), (b) (6)	11 Mar 2021 17:24:39

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:24:39

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Mar 2021 17:24:39

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:24:39

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '02 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 17:24:39

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 17:24:39

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:05
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Carlos Fierro (b) (4)	08 Apr 2021 06:42:02 07 Apr 2021 20:21:04
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:52:12
DataPoint Un-verified.	Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:51:22
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	07 Apr 2021 19:51:22
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 14:09:46
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 17:24:39

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Un-verified.	(b) (4) Karol Moore (b) (4)	07 Apr 2021 19:51:22
User entered '07 Mar 2021' reason for change: Data Entry Error	(b) (4) Karol Moore (b) (4)	07 Apr 2021 19:51:22
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 17:24:39

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:05
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:18:14
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 17:24:39

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:05
User entered empty.	System	11 Mar 2021 17:24:39

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:05
User entered empty.	System	11 Mar 2021 17:24:39

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:05
User entered empty.	System	11 Mar 2021 17:24:39

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN SODIUM, PRODUCTSYNONYM: ANCEF [CEFAZOLIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 11:40:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	08 Apr 2021 11:40:51
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
Data point term sent to Coder	(b) (4)	
User closed query '	System	07 Apr 2021 15:49:17
DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.	System	07 Apr 2021 15:49:15
' (Site from System).		
Query '	Karol Moore (b) (4)	07 Apr 2021 15:49:15
DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.	(b) (4)	
' answered with 'UPDATED' (Site from System).		
User entered 'ANCEF (Cefazolin)' reason for change: Data Entry Error	Karol Moore (b) (4)	07 Apr 2021 15:48:24
User opened query '	(b) (4)	
DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.	Coder Import (b) (4)	30 Mar 2021 09:06:22
' (Site from System).	(b) (4)	
Data point term sent to Coder	System	25 Mar 2021 23:25:03
Data point term sent to Coder	System	23 Mar 2021 21:36:53
User entered 'ANcef'	(b) (4), (b) (6)	23 Mar 2021 21:36:07

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:36:07

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
User entered 'Perioperative prophylaxis'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:36:07

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:36:07

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:36:07

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:36:07

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:36:07

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:36:07

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Mar 2021 23:24:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Mar 2021 23:24:14
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 23:24:14
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 21:36:07
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 21:36:07

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:36:07

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:36:07

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:36:07

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:36:07

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:36:07

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:08
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 20:21:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:36:07

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:08
User entered empty.	System	23 Mar 2021 21:36:07

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:08
User entered empty.	System	23 Mar 2021 21:36:07

US3312434

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:02:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:08
User entered empty.	System	23 Mar 2021 21:36:07

US3312434

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:02:25

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:26:04
User signature succeeded.	Carlos Fierro (b) (4)	28 Apr 2021 21:58:59
User closed query 'Per ETTR: According to SAE "Severe Osteoarthritis with avascular necrosis right hip", Concomitant procedure was performed, but the same is missing in this folder. Please update as applicable, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:06:28
Query 'Per ETTR: According to SAE "Severe Osteoarthritis with avascular necrosis right hip", Concomitant procedure was performed, but the same is missing in this folder. Please update as applicable, thanks.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	15 Mar 2021 18:13:38
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 18:13:29
User opened query 'Per ETTR: According to SAE "Severe Osteoarthritis with avascular necrosis right hip", Concomitant procedure was performed, but the same is missing in this folder. Please update as applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 19:01:31
User entered 'No (N)'	(b) (4), (b) (6)	19 Feb 2021 15:24:01

US3312434

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:02:25

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:14:59

US3312434

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:02:25

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'RIGHT HIP REPLACEMENT'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:14:59

US3312434

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:02:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:14:59

US3312434

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:02:25

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:14:59

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'USA-US300-2021-MRNA-1273-P301000017'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Yes (Y)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Yes (Y)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Carlos'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Fierro'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered '16300 College Blvd'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Shawnee'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'KS'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered '66219'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 14:24:56
User entered 'US'	System	22 Feb 2021 16:10:53

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 17:35:05
User entered '4'	System	18 Mar 2021 11:55:43
User entered '3'	System	16 Mar 2021 14:39:05
User entered '2'	System	25 Feb 2021 14:25:22
User entered '1'	System	22 Feb 2021 16:10:53

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'USA-US300-2021-MRNA-1273-P301000017'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Yes (Y)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Yes (Y)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Carlos'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Fierro'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered '16300 College Blvd'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Shawnee'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'KS'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered '66219'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 14:24:56
User entered 'US'	System	22 Feb 2021 16:10:53

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 17:35:05
User entered '4'	System	18 Mar 2021 11:55:43
User entered '3'	System	16 Mar 2021 14:39:05
User entered '2'	System	25 Feb 2021 14:25:22
User entered '1'	System	22 Feb 2021 16:10:53

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:02:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
User entered '22/Feb/2021 10:10'	System	22 Feb 2021 16:10:53

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:02:25

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.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 14:25:03
User entered 'I'	(b) (4), (b) (6)	22 Feb 2021 16:10:53

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'USA-US300-2021-MRNA-1273-P301000017'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Yes (Y)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Yes (Y)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Carlos'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Fierro'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered '16300 College Blvd'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Shawnee'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'KS'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered '66219'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 14:24:56
User entered 'US'	System	22 Feb 2021 16:10:53

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 17:35:05
User entered '4'	System	18 Mar 2021 11:55:43
User entered '3'	System	16 Mar 2021 14:39:05
User entered '2'	System	25 Feb 2021 14:25:22
User entered '1'	System	22 Feb 2021 16:10:53

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:02:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
User entered '25/Feb/2021 09:25'	System	25 Feb 2021 14:25:22

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:02:25

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.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 14:38:50
User entered 'I'	(b) (4), (b) (6)	25 Feb 2021 14:25:22

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'USA-US300-2021-MRNA-1273-P301000017'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Yes (Y)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Yes (Y)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Carlos'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Fierro'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered '16300 College Blvd'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Shawnee'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'KS'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered '66219'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 14:24:56
User entered 'US'	System	22 Feb 2021 16:10:53

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 17:35:05
User entered '4'	System	18 Mar 2021 11:55:43
User entered '3'	System	16 Mar 2021 14:39:05
User entered '2'	System	25 Feb 2021 14:25:22
User entered '1'	System	22 Feb 2021 16:10:53

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:02:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
User entered '16/Mar/2021 09:39'	System	16 Mar 2021 14:39:05

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:02:25

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.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
User entered 'I'	(b) (4), (b) (6)	16 Mar 2021 14:39:05

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'USA-US300-2021-MRNA-1273-P301000017'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Yes (Y)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Yes (Y)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Carlos'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Fierro'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered '16300 College Blvd'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Shawnee'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'KS'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered '66219'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 14:24:56
User entered 'US'	System	22 Feb 2021 16:10:53

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 17:35:05
User entered '4'	System	18 Mar 2021 11:55:43
User entered '3'	System	16 Mar 2021 14:39:05
User entered '2'	System	25 Feb 2021 14:25:22
User entered '1'	System	22 Feb 2021 16:10:53

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:02:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
User entered '18/Mar/2021 07:55'	System	18 Mar 2021 11:55:43

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:02:25

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.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
User entered 'I'	(b) (4), (b) (6)	18 Mar 2021 11:55:43

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'USA-US300-2021-MRNA-1273-P301000017'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Yes (Y)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Yes (Y)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'No (N)'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Carlos'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Fierro'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered '16300 College Blvd'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'Shawnee'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered 'KS'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:10:43
User entered '66219'	System	22 Feb 2021 16:02:19

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:11
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 14:24:56
User entered 'US'	System	22 Feb 2021 16:10:53

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 17:35:05
User entered '4'	System	18 Mar 2021 11:55:43
User entered '3'	System	16 Mar 2021 14:39:05
User entered '2'	System	25 Feb 2021 14:25:22
User entered '1'	System	22 Feb 2021 16:10:53

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:02:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered '24/Mar/2021 13:34'	(b) (4) System	24 Mar 2021 17:35:05

US3312434

Folder: SAE USA-US300-2021-MRNA-1273-P301000017

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:02:25

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.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 02:32:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:35:05