

US3322429 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3322429

Form: Participant Creation

Data signed: (b) (4) 26 Feb 2021 04:15:00

Generated On: 09 Jun 2021 17:07:21

Participant ID

US3322429

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

US3322429

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:15:03

Generated On: 09 Jun 2021 17:07:21

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Feb 2021 04:15:03

Generated On: 09 Jun 2021 17:07:21

Date of Birth (MMM yyyy)	(b) (6) 1976
Age	44
Age Units	YEARS
Age (Derived)	44
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	True
If race is Other, specify	NATIVE SOUTH AMERICAN
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Feb 2021 04:15:03

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Date of Informed Consent (<i>dd MMM yyyy</i>)	14 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input checked="" 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) 26 Feb 2021 04:15:03

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Feb 2021 04:15:03

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Feb 2021 04:15:03

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Condition	HYPOTHYROIDISM
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 (2)

Data signed: (b) (4) 26 Feb 2021 04:15:03

Generated On: 09 Jun 2021 17:07:21

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Feb 2021 04:15:03

Generated On: 09 Jun 2021 17:07:21

Condition	LEPTIN RESISTANCE (WEIGHT GAIN)
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) 26 Feb 2021 04:15:03

Generated On: 09 Jun 2021 17:07:21

Condition	ROTATOR CUFF REPAIR
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Feb 2021 04:15:03

Generated On: 09 Jun 2021 17:07:21

Condition	ROTATOR CUFF INJURY -RIGHT
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAR 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	MAR 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Feb 2021 04:15:03

Generated On: 09 Jun 2021 17:07:21

Condition	BILATERAL TUBAL LIGATION
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 04:15:03

Generated On: 09 Jun 2021 17:07:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	09:24 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 09:24
Height (<i>xxx.x</i>)	69 in
Weight (<i>xxx.x</i>)	237 lb
BMI (<i>xxx.x</i>)	35.07196 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 04:15:03

Generated On: 09 Jun 2021 17:07:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 OCT 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) 26 Feb 2021 04:15:03

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Date of assessment (*dd MMM yyyy*) 14 OCT 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*) _____
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 26 Feb 2021 04:15:03

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Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	14 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Feb 2021 04:15:03

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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

DIRECTOR FOOD SERVICE
SALE .

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) 26 Feb 2021 04:15:03

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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	-WORKS OUTSIDE HOME>2/WEEK, CONTACT >5/DAY . -CHILDREN GOES TO SCHOOL/DAYCARE IN PERSON - ATTENDS GATHERING OF 10 PPL 2/MONTH (2) DINES IN 1/WEEK GYM 2/WEEK.

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:15:03

Generated On: 09 Jun 2021 17:07:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Feb 2021 04:15:03

Generated On: 09 Jun 2021 17:07:21

What was the date of randomization? (dd MMM yyyy) 14 OCT 2020

What was the participant's randomization number? 117065

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) 26 Feb 2021 04:15:04

Generated On: 09 Jun 2021 17:07:21

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) 26 Feb 2021 04:15:04

Generated On: 09 Jun 2021 17:07:21

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)	14 OCT 2020
Time of assessment (00:00-23:59)	09:29 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 09:29
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 04:15:04

Generated On: 09 Jun 2021 17:07:21

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)	14 OCT 2020
Time of assessment (00:00-23:59)	11:34 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 11:34
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	97 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	54 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 04:15:03

Generated On: 09 Jun 2021 17:07:21

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: Pregnancy Test

Data signed: (b) (4) 26 Feb 2021 04:15:03

Generated On: 09 Jun 2021 17:07:21

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☐

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 04:15:03

Generated On: 09 Jun 2021 17:07:21

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 10:57 (24 HR)

Treatment Date and Time (derived) 14 OCT 2020 10:57

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 04:15:03

Generated On: 09 Jun 2021 17:07:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 OCT 2020
Collection time (00:00-23:59)	10:40 (24 HR)
Collection date and time (derived)	14 OCT 2020 10:40

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 04:15:03

Generated On: 09 Jun 2021 17:07:21

Collection date (dd MMM yyyy)			14 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:37	14 OCT 2020 10:37
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:15:03

Generated On: 09 Jun 2021 17:07:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 11:34

PC Open Date & Time

14 OCT 2020 11:17

PC Close Date & Time

14 OCT 2020 13:47

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °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	14 OCT 2020 21:06
PC Open Date & Time	14 OCT 2020 14:42
PC Close Date & Time	15 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 20:17

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:21

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 22:13

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:21

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 22:45

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:21

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 21:58

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 20:43

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:21

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 20:39

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

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

14 OCT 2020 11:35

PC Open Date & Time

14 OCT 2020 11:17

PC Close Date & Time

14 OCT 2020 13:47

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

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

2

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 21:05

PC Open Date & Time

14 OCT 2020 14:42

PC Close Date & Time

15 OCT 2020 11:59

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

1

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 20:21

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:21

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

16 OCT 2020 22:14

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:21

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

17 OCT 2020 22:46

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:21

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

18 OCT 2020 21:58

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:21

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

19 OCT 2020 20:43

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:21

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

20 OCT 2020 20:39

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 11:35
PC Open Date & Time	14 OCT 2020 11:17
PC Close Date & Time	14 OCT 2020 13:47

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 21:06
PC Open Date & Time	14 OCT 2020 14:42
PC Close Date & Time	15 OCT 2020 11:59

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

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 ☒

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 20:21
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

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)

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 22:14
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

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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US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 22:46
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

56 of 2406

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 21:59
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 20:43
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

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

60 of 2406

EAB) (1725)

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:15:03

Generated On: 09 Jun 2021 17:07:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322429

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:15:02

Generated On: 09 Jun 2021 17:07:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322429

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:15:02

Generated On: 09 Jun 2021 17:07:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322429

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:15:02

Generated On: 09 Jun 2021 17:07:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322429

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:15:02

Generated On: 09 Jun 2021 17:07:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322429

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:15:02

Generated On: 09 Jun 2021 17:07:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322429

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:15:04

Generated On: 09 Jun 2021 17:07:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 NOV 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

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 04:15:04

Generated On: 09 Jun 2021 17:07:21

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)	10 NOV 2020
Time of assessment (00:00-23:59)	10:38 (24 HR)
Vital Signs Date and Time (derived)	10 NOV 2020 10:38
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 04:15:04

Generated On: 09 Jun 2021 17:07:21

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)	10 NOV 2020
Time of assessment (00:00-23:59)	12:29 (24 HR)
Vital Signs Date and Time (derived)	10 NOV 2020 12:29
Temperature (xxx.x)	96.1 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3322429

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 04:15:04

Generated On: 09 Jun 2021 17:07:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 NOV 2020

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

US3322429

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 26 Feb 2021 04:15:04

Generated On: 09 Jun 2021 17:07:21

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 10 NOV 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3322429

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 04:15:04

Generated On: 09 Jun 2021 17:07:21

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) 10 NOV 2020

What was the treatment time? (00:00-23:59) 12:08 (24 HR)

Treatment Date and Time (derived) 10 NOV 2020 12:08

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

US3322429

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 04:15:04

Generated On: 09 Jun 2021 17:07:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 NOV 2020

Collection time (00:00-23:59)

11:08 (24 HR)

Collection date and time (derived)

10 NOV 2020 11:08

US3322429

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 04:15:04

Generated On: 09 Jun 2021 17:07:21

Collection date (dd MMM yyyy)			10 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:05	10 NOV 2020 11:05
Nasopharyngeal Swab 2	No		

US3322429

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:15:04

Generated On: 09 Jun 2021 17:07:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

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

96.1 °F

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

Yes ☐
No ☒

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

PC Time Stamp 10 NOV 2020 12:29

PC Open Date & Time 10 NOV 2020 12:28

PC Close Date & Time 10 NOV 2020 14:58

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp	10 NOV 2020 20:44
PC Open Date & Time	10 NOV 2020 15:53
PC Close Date & Time	11 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:21

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

100.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 NOV 2020 17:03

PC Open Date & Time

11 NOV 2020 12:00

PC Close Date & Time

12 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:21

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	12 NOV 2020 16:51
PC Open Date & Time	12 NOV 2020 12:00
PC Close Date & Time	13 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:21

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

13 NOV 2020 19:24

PC Open Date & Time

13 NOV 2020 12:00

PC Close Date & Time

14 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:21

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

97.8 °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

14 NOV 2020 21:42

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:21

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

97.8 °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

15 NOV 2020 21:24

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 NOV 2020 21:09

PC Open Date & Time

16 NOV 2020 12:00

PC Close Date & Time

17 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

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

10 NOV 2020 12:30

PC Open Date & Time

10 NOV 2020 12:28

PC Close Date & Time

10 NOV 2020 14:58

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

20

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

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

Yes ☒

No ☐

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

20

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 NOV 2020 20:47

PC Open Date & Time

10 NOV 2020 15:53

PC Close Date & Time

11 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:21

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 ☐

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

20

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

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

Yes ☒

No ☐

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

20

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 NOV 2020 17:04

PC Open Date & Time

11 NOV 2020 12:00

PC Close Date & Time

12 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:21

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 ☐

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

70

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

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

Yes ☒

No ☐

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

70

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 NOV 2020 16:52

PC Open Date & Time

12 NOV 2020 12:00

PC Close Date & Time

13 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:21

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 ☐

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

50

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

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

Yes ☒

No ☐

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

50

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 NOV 2020 19:27

PC Open Date & Time

13 NOV 2020 12:00

PC Close Date & Time

14 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:21

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 ☐

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

40

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 NOV 2020 21:43

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:21

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

15

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 NOV 2020 21:26

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:21

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

15

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 NOV 2020 21:09

PC Open Date & Time

16 NOV 2020 12:00

PC Close Date & Time

17 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

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

No ☒

Yes ☐

PC Time stamp	10 NOV 2020 12:30
PC Open Date & Time	10 NOV 2020 12:28
PC Close Date & Time	10 NOV 2020 14:58

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

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

No ☒

Yes ☐

PC Time stamp	10 NOV 2020 20:48
PC Open Date & Time	10 NOV 2020 15:53
PC Close Date & Time	11 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

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)

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

Yes <input type="checkbox"/>	
PC Time stamp	11 NOV 2020 17:04
PC Open Date & Time	11 NOV 2020 12:00
PC Close Date & Time	12 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

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)

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

Yes <input type="checkbox"/>	
PC Time stamp	12 NOV 2020 16:52
PC Open Date & Time	12 NOV 2020 12:00
PC Close Date & Time	13 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

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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Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

Yes <input type="checkbox"/>	
PC Time stamp	13 NOV 2020 19:27
PC Open Date & Time	13 NOV 2020 12:00
PC Close Date & Time	14 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

Yes <input type="checkbox"/>	
PC Time stamp	14 NOV 2020 21:43
PC Open Date & Time	14 NOV 2020 12:00
PC Close Date & Time	15 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

Yes <input type="checkbox"/>	
PC Time stamp	15 NOV 2020 21:27
PC Open Date & Time	15 NOV 2020 12:00
PC Close Date & Time	16 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

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)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

Yes <input type="checkbox"/>	
PC Time stamp	16 NOV 2020 21:10
PC Open Date & Time	16 NOV 2020 12:00
PC Close Date & Time	17 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 8

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

Yes ☐

No ☐

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

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

PC Time stamp

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 9

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

Yes ☒

No ☐

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

10

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

PC Time stamp 19 NOV 2020 07:58

PC Open Date & Time 18 NOV 2020 12:00

PC Close Date & Time 19 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: Swelling_Day(10)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT	DAY 10
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="checkbox"/>
	No <input checked="" type="radio"/>
PC Time stamp	19 NOV 2020 23:10
PC Open Date & Time	19 NOV 2020 12:00
PC Close Date & Time	20 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 NOV 2020 07:58
PC Open Date & Time	18 NOV 2020 12:00
PC Close Date & Time	19 NOV 2020 11:59

US3322429

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 NOV 2020 23:10
PC Open Date & Time	19 NOV 2020 12:00
PC Close Date & Time	20 NOV 2020 11:59

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Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:15:02

Generated On: 09 Jun 2021 17:07:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322429

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:15:02

Generated On: 09 Jun 2021 17:07:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322429

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:15:02

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:15:02

Generated On: 09 Jun 2021 17:07:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322429

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:15:02

Generated On: 09 Jun 2021 17:07:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322429

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:15:02

Generated On: 09 Jun 2021 17:07:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322429

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:15:04

Generated On: 09 Jun 2021 17:07:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 DEC 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

US3322429

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 04:15:04

Generated On: 09 Jun 2021 17:07:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 DEC 2020
Time of assessment (00:00-23:59)	09:03 (24 HR)
Vital Signs Date and Time (derived)	08 DEC 2020 09:03
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)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322429

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 04:15:04

Generated On: 09 Jun 2021 17:07:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 DEC 2020

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

US3322429

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 04:15:04

Generated On: 09 Jun 2021 17:07:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 DEC 2020
Collection time (00:00-23:59)	09:33 (24 HR)
Collection date and time (derived)	08 DEC 2020 09:33

US3322429

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:15:04

Generated On: 09 Jun 2021 17:07:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT	DAY 61
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 DEC 2020 10:49:10
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT	DAY 68
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	18 DEC 2020 12:09:50
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT	DAY 75
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 DEC 2020 12:22:34
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	01 JAN 2021 10:17:35
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	08 JAN 2021 04:19:55
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Please contact your study clinic immediately. Click below to confirm that you have read this 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	15 JAN 2021 11:13:28
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

22 JAN 2021 17:42:28

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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	01 FEB 2021 08:44:23
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 09:21:27

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 09:04:06
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 10:27:56
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 FEB 2021 16:09:49
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

08 MAR 2021 14:19:42

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	12 MAR 2021 10:47:57
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

19 MAR 2021 10:36:20

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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	30 MAR 2021 08:36:43
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

02 APR 2021 16:35:19

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 05:34:11

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 <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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 APR 2021 09:26:47
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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	23 APR 2021 10:26:33
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAY 2021 23:49:09
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

Date and time of submission	
Patient Cloud Open Date & Time	14 MAY 2021 00:01
Patient Cloud Close Date & Time	18 MAY 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 243

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

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

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

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

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

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

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

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 250

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

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

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JUN 2021 00:01
Patient Cloud Close Date & Time	22 JUN 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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"/>

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JUL 2021 00:01
Patient Cloud Close Date & Time	06 JUL 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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°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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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"/>

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 334

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

Date and time of submission	
Patient Cloud Open Date & Time	10 SEP 2021 00:01
Patient Cloud Close Date & Time	14 SEP 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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"/>

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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°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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 NOV 2021 00:01
Patient Cloud Close Date & Time	16 NOV 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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"/>

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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°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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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"/>

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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"/>

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 FEB 2022 00:01
Patient Cloud Close Date & Time	08 FEB 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 FEB 2022 00:01
Patient Cloud Close Date & Time	22 FEB 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 APR 2022 00:01
Patient Cloud Close Date & Time	26 APR 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2022 00:01
Patient Cloud Close Date & Time	14 JUN 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 2022 00:01
Patient Cloud Close Date & Time	26 JUL 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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°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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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"/>

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 2022 00:01
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Patient Cloud Close Date & Time	18 OCT 2022 23:59
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US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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"/>

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	18 NOV 2022 00:01
Patient Cloud Close Date & Time	22 NOV 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

25 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

02 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	09 DEC 2022 00:01
Patient Cloud Close Date & Time	13 DEC 2022 23:59

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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"/>

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	16 DEC 2022 00:01
Patient Cloud Close Date & Time	20 DEC 2022 23:59

US3322429

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:07:21

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		08 MAR 2021 14:19:30

US3322429

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:15:03

Generated On: 09 Jun 2021 17:07:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322429

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:15:03

Generated On: 09 Jun 2021 17:07:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322429

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:15:02

Generated On: 09 Jun 2021 17:07:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322429

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:15:02

Generated On: 09 Jun 2021 17:07:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322429

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 22:14:06

Generated On: 09 Jun 2021 17:07:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322429

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 22:14:06

Generated On: 09 Jun 2021 17:07:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322429

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322429

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322429

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:21

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

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

Folder OID	_____
------------	-------

US3322429

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3322429

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:21

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.

US3322429

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:21

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<input type="text"/>
Collection time (<i>00:00-23:59</i>)	<input type="text"/>
Collection date and time (derived)	<input type="text"/>

US3322429

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3322429

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:07:21

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"/>

US3322429

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:07:21

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3322429

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

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:15:02

Generated On: 09 Jun 2021 17:07:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 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	UNBLND_DECIDE

US3322429

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

Form: Unblinding

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

Date of updated informed consent (*dd MMM yyyy*) 03 FEB 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (*dd MMM yyyy*) 18 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3322429

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 04:15:02

Generated On: 09 Jun 2021 17:07:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	03 FEB 2021
Collection time (00:00-23:59)	13:28 (24 HR)
Collection date and time (derived)	03 FEB 2021 13:28

US3322429

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Feb 2021 04:15:02

Generated On: 09 Jun 2021 17:07:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	03 FEB 2021
Collection time (00:00 - 23:59)	13:23
Collection Date and Time (derived)	03 FEB 2021 13:23

US3322429

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Feb 2021 04:15:02

Generated On: 09 Jun 2021 17:07:21

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 16:20:45

Generated On: 09 Jun 2021 17:07:21

AEID	
Adverse event	RHINORRHEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	08 DEC 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)	08 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 16:20:45

Generated On: 09 Jun 2021 17:07:21

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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3322429

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 16:20:45

Generated On: 09 Jun 2021 17:07:21

AEID

Adverse event

INJECTION SITE SWELLING OF
LEFT UPPER ARM

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 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)

19 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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US3322429

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 16:20:45

Generated On: 09 Jun 2021 17:07:21

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 16:20:45

Generated On: 09 Jun 2021 17:07:21

AEID	
Adverse event	COUGH
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)	08 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 16:20:45

Generated On: 09 Jun 2021 17:07:21

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 16:20:45

Generated On: 09 Jun 2021 17:07:21

AEID

Adverse event

SHORTNESS OF BREATH

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

08 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

09 JAN 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 (4)

Data signed: (b) (4) 28 Apr 2021 16:20:45

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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:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 16:20:45

Generated On: 09 Jun 2021 17:07:21

AEID	USA-US060-2021-MRNA-1273-P30 1000009
Adverse event	GATROINTESTINAL STROMAL TUMOR
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)	31 DEC 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)	31 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	31 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	01 JAN 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) 28 Apr 2021 16:20:45

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 16:20:45

Generated On: 09 Jun 2021 17:07:21

DURING SAFETY CALL TODAY,
PATIENT REPORTS THAT A
GASTROINTESTINAL STROMAL
TUMOR WAS FOUND
INCIDENTALLY ON 31DEC2020
DURING HER ELECTIVE
GASTRIC BYPASS SURGERY.
PATIENT HAD A NORMAL
HOSPITALIZATION AND
RECOVERED WELL AND WAS
DISCHARGED IN STABLE
CONDITION ON 01JAN2021.
PATIENT HAD OUTPATIENT
FOLLOW UP AT MDANDERSON
REGARDING HER
GASTROINTESTINAL STROMAL
TUMOR WITH AN ONCOLOGIST.
DUE TO THE SIZE OF TUMOR,
PATIENT WAS TOLD THAT
REOCURRENCE IS 0%. HAD CT
OF ABDOMEN AND LUNGS
WHICH IS REPORTED AS
NEGATIVE PER PATIENT. HER
ENDOSCOPY PRIOR TO
GASTRIC BYPASS WAS ONLY
SIGNIFICANT FOR A BENIGN
POLYP. PATIENT WILL HAVE
SCHEDULED FOLLOW UP
EVERY 6 MONTHS FOR
SEVERAL YEARS. MEDICAL
RECORD RELEASE HAS
ALREADY BEEN OBTAINED.
WILL AWAIT REVIEW OF
PENDING RECORDS.

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 16:20:45

Generated On: 09 Jun 2021 17:07:21

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 16:20:45

Generated On: 09 Jun 2021 17:07:21

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 16:20:45

Generated On: 09 Jun 2021 17:07:21

AEID	
Adverse event	CHAGA'S DISEASE
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)	12 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 16:20:45

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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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Feb 2021 04:15:02

Generated On: 09 Jun 2021 17:07:21

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) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

Name of Medication VYVANSE

Prophylaxis Yes ☐
No ☒

Indication ATTENTION DEFICIT DISORDER

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

Name of Medication UNITHROID

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

	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 (3)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

Name of Medication VICTOZA

Prophylaxis Yes ☐
No ☒

Indication LEPTIN RESISTANCE (WEIGHT CONTROL)

Dose per administration 1.8

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN AND MYALGIA

Dose per administration 800

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 (4)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

	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)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 NOV 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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 (5)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication FEVER

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 (5)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

	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)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 11 NOV 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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 (6)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

	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)		12 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)		12 NOV 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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 (7)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

Name of Medication HYDROMORPHONE

Prophylaxis Yes ☒
No ☐

Indication GASTROINTESTINAL STROMAL
TUMOR

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

	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)		31 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 JAN 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 (8)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication GASTROINTESTINAL STROMAL
TUMOR

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

	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)		31 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 JAN 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 (9)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication GASTROINTESTINAL STROMAL
TUMOR

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

	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)		21 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 JAN 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 (10)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

Name of Medication ENOXAPARIN

Prophylaxis Yes ☐
No ☒

Indication GASTROINTESTINAL STROMAL
TUMOR

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

	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)	31 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

Name of Medication KETOROLAC

Prophylaxis Yes ☐
No ☒

Indication GASTROINTESTINAL STROMAL
TUMOR

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

	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)	31 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication REFLUX

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	01 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication NAUSEA AND VOMITING

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

	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)		31 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

Name of Medication PROMETHAZINE

Prophylaxis Yes ☐
No ☒

Indication NAUSEA/ VOMITING

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

	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)		31 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 JAN 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 (15)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

Name of Medication URSODIOL (URSO)

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF GALLSTONES

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

	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)	12 JAN 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

Name of Medication SUCRALFATE (CARAFATE)

Prophylaxis Yes ☒
No ☐

Indication PREVENT ULCERS

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

	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)	12 JAN 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)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

Name of Medication OMEPRAZOLE (PRILOSEC)

Prophylaxis Yes ☐
No ☒

Indication TREATMENT OF GERD

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

	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)		12 JAN 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"/>

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

Name of Medication BENZNIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication CHAGAS DISEASE TREATMENT

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

389 of 2406

EAB) (1725)

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 16:40:25

Generated On: 09 Jun 2021 17:07:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Feb 2021 04:15:02

Generated On: 09 Jun 2021 17:07:21

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 24 Mar 2021 22:14:06

Generated On: 09 Jun 2021 17:07:21

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
13 NOV 2020	ESOPHAGOGASTRODUODENOSC OPY	Diagnostic	
20 NOV 2020	PCR COVID-19 TEST	Diagnostic	
04 DEC 2020	PCR COVID-19 TEST	Diagnostic	
31 DEC 2020	GASTRIC BYPASS (ELECTIVE)	Medical History	
08 JAN 2021	RAPID COVID-19 TEST (NEGATIVE)	Diagnostic	
13 JAN 2021	ORAL COVID-19 TEST (RESULTS PENDING)	Diagnostic	
08 JAN 2021	CT SCAN WITH CONTRAST (OF LUNGS)	Diagnostic	
31 DEC 2020	REMOVAL OF GASTROINTESTINAL STROMAL TUMOR	Adverse Event	
25 FEB 2021	PCR COVID-19 (NASAL SWAB TEST) NEGATIVE	Diagnostic	
19 FEB 2021	SUTURE REPAIR OF LEFT LOWER LEG LACERATION	Adverse Event	

US3322429

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:07:21

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

US3322429

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:07:21

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 ☐

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 24 Mar 2021 22:14:06

Generated On: 09 Jun 2021 17:07:21

SAEID	USA-US060-2021-MRNA-1273-P301000009
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Mar 2021 22:14:06

Generated On: 09 Jun 2021 17:07:21

SAEID	USA-US060-2021-MRNA-1273-P301000009
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	08/FEB/2021 13:33
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

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Mar 2021 22:14:06

Generated On: 09 Jun 2021 17:07:21

SAEID	USA-US060-2021-MRNA-1273-P301000009
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/FEB/2021 10:08
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

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 24 Mar 2021 22:14:06

Generated On: 09 Jun 2021 17:07:21

SAEID	USA-US060-2021-MRNA-1273-P301000009
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/FEB/2021 14:42
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

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Data signed: (b) (4) 24 Mar 2021 22:14:06

Generated On: 09 Jun 2021 17:07:21

SAEID	USA-US060-2021-MRNA-1273-P301000009
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	26/FEB/2021 10:13
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

US3322429 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

US3322429

Form: Participant Creation

Generated On: 09 Jun 2021 17:07:21

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'US3322429'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Oct 2020 14:23:34

US3322429

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:07:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:51:57

US3322429

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '14 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Oct 2020 14:23:35

US3322429

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:07:21

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 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Clinic (Clinic)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:51:57

US3322429

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:07:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered 'SCRN'	System	14 Oct 2020 16:51:57

US3322429

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:21

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered (b) (6) 1976'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Oct 2020 14:23:36

US3322429

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:21

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '44'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:53:27

US3322429

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:21

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered 'YEARS'	System	14 Oct 2020 16:53:27

US3322429

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:21

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered '44'	System	14 Oct 2020 16:04:44

US3322429

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:21

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Female (F)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:53:27

US3322429

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:21

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:53:27

US3322429

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:21

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:53:27

US3322429

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:21

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:53:27

US3322429

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:21

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:53:27

US3322429

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:21

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:53:27

US3322429

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:21

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:53:27

US3322429

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'I'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:53:27

US3322429

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:21

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'NATIVE SOUTH AMERICAN'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:53:27

US3322429

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:21

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:53:27

US3322429

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:21

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:53:27

US3322429

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:21

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '14 Oct 2020'	Frances Saubon (b) (4)	14 Oct 2020 16:04:44

US3322429

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered 'Oct 2020'	System	14 Oct 2020 16:04:44

US3322429

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered '2020'	System	14 Oct 2020 16:04:44

US3322429

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:21

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Amendment 4 (4)'	Frances Saubon (b) (4)	14 Oct 2020 16:04:44

US3322429

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Frances Saubon (b) (4)	14 Oct 2020 16:04:44

US3322429

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:21

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Frances Saubon (b) (4)	14 Oct 2020 16:04:44

US3322429

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:21

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Frances Saubon (b) (4)	14 Oct 2020 16:04:44

US3322429

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:21

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Frances Saubon (b) (4)	14 Oct 2020 16:04:44

US3322429

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:21

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Oct 2020 14:23:35

US3322429

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:21

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered '1'	System	14 Oct 2020 16:04:50

US3322429

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Frances Saubon (b) (4)	14 Oct 2020 16:04:50

US3322429

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:07:21

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:53:36

US3322429

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 16:55:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 16:55:39
Data point term sent to Coder	System	14 Oct 2020 16:54:15
User entered 'Hypothyroidism'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:53:53

US3322429

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'UN UNK 2018'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:53:53

US3322429

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:53:53

US3322429

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:53:53

US3322429

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:53:53

US3322429

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:53:53

US3322429

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered 'Jan 2018'	System	14 Oct 2020 16:53:53

US3322429

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered '2018'	System	14 Oct 2020 16:53:53

US3322429

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered empty.	System	14 Oct 2020 16:53:53

US3322429

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered empty.	System	14 Oct 2020 16:53:53

US3322429

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User coded data point as SOC: Psychiatric disorders, HLTG: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit disorder - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 16:55:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 16:55:39
Data point term sent to Coder	System	14 Oct 2020 16:54:18
User entered 'Attention Deficit Disorder'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:54:10

US3322429

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'UN UNK 2019'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:54:10

US3322429

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:54:10

US3322429

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:54:10

US3322429

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:54:10

US3322429

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:54:10

US3322429

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered 'Jan 2019'	System	14 Oct 2020 16:54:10

US3322429

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered '2019'	System	14 Oct 2020 16:54:10

US3322429

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered empty.	System	14 Oct 2020 16:54:10

US3322429

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered empty.	System	14 Oct 2020 16:54:10

US3322429

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User coded data point as SOC: Investigations, HLGT: Physical examination and organ system status topics, HLT: Physical examination procedures and organ system status, PT: Weight increased, LLT: Weight gain - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 00:11:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 00:11:55
Data point term sent to Coder	System	14 Oct 2020 16:55:21
User entered 'Leptin resistance (weight gain)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:54:34

US3322429

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'UN UNK 2018'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:54:34

US3322429

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:54:34

US3322429

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:54:34

US3322429

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:54:34

US3322429

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:54:34

US3322429

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered 'Jan 2018'	System	14 Oct 2020 16:54:34

US3322429

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered '2018'	System	14 Oct 2020 16:54:34

US3322429

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered empty.	System	14 Oct 2020 16:54:34

US3322429

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered empty.	System	14 Oct 2020 16:54:34

US3322429

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 16:56:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 16:56:28
Data point term sent to Coder	System	14 Oct 2020 16:55:21
User entered 'Rotator cuff repair'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:54:53

US3322429

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'UN UNK 2018'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:54:53

US3322429

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:54:53

US3322429

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:54:53

US3322429

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'UN UNK 2018'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:54:53

US3322429

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:54:53

US3322429

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered 'Jan 2018'	System	14 Oct 2020 16:54:53

US3322429

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered '2018'	System	14 Oct 2020 16:54:53

US3322429

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered 'Jan 2018'	System	14 Oct 2020 16:54:53

US3322429

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered '2018'	System	14 Oct 2020 16:54:53

US3322429

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:07:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff injury - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 04:25:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 04:25:29
Data point term sent to Coder	System	14 Oct 2020 16:55:24
User entered 'Rotator Cuff Injury -Right'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:55:19

US3322429

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'UN UNK 2018'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:55:19

US3322429

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:55:19

US3322429

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:07:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:55:19

US3322429

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'UN Mar 2018'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:55:19

US3322429

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:07:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:55:19

US3322429

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:07:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered 'Jan 2018'	System	14 Oct 2020 16:55:19

US3322429

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:07:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered '2018'	System	14 Oct 2020 16:55:19

US3322429

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered 'Mar 2018'	System	14 Oct 2020 16:55:19

US3322429

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered '2018'	System	14 Oct 2020 16:55:19

US3322429

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User closed query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:28:28
Query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.' answered with 'Per source, Bilateral Tubal Ligation surgery failed, subject conceived after procedure. Thus, subject husband had vasectomy performed.' (Site from DM).	Blessing Felix-Okoroji (b) (4)	26 Oct 2020 16:00:36
User opened query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 07:06:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:57:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:57:34
Data point term sent to Coder	System	14 Oct 2020 16:56:25
User entered 'Bilateral Tubal Ligation'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:55:39

US3322429

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'UN UNK 2009'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:55:39

US3322429

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:55:39

US3322429

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:55:39

US3322429

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'UN UNK 2009'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:55:39

US3322429

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:55:39

US3322429

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered 'Jan 2009'	System	14 Oct 2020 16:55:39

US3322429

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered '2009'	System	14 Oct 2020 16:55:39

US3322429

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered 'Jan 2009'	System	14 Oct 2020 16:55:39

US3322429

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered '2009'	System	14 Oct 2020 16:55:39

US3322429

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:56:27

US3322429

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '14 Oct 2020'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:56:27

US3322429

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '09:24'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:56:27

US3322429

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered '14 Oct 2020 09:24'	System	14 Oct 2020 16:56:27

US3322429

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '69' in	(b) (4)	
	Blessing Felix-Okoroji	14 Oct 2020 16:56:27
DataPoint set to visible.	(b) (4)	
	System	14 Oct 2020 16:04:50

US3322429

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '237' lb	(b) (4) Blessing Felix-Okoroji	14 Oct 2020 16:56:27
DataPoint set to visible.	(b) (4) System	14 Oct 2020 16:04:50

US3322429

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered '35.07196'	System	14 Oct 2020 16:56:27
DataPoint set to visible.	System	14 Oct 2020 16:04:50

US3322429

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered 'kg/m2'	System	14 Oct 2020 16:56:27
DataPoint set to visible.	System	14 Oct 2020 16:04:50

US3322429

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered missing code ND - Not Done.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:56:27

US3322429

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:56:27

US3322429

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:56:27

US3322429

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered missing code ND - Not Done.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:56:27

US3322429

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered 'bpm'	System	14 Oct 2020 16:56:27

US3322429

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered missing code ND - Not Done.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:56:27

US3322429

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered 'breaths/min'	System	14 Oct 2020 16:56:27

US3322429

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered missing code ND - Not Done.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:56:27

US3322429

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered 'mmHg'	System	14 Oct 2020 16:56:27

US3322429

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered missing code ND - Not Done.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:56:27

US3322429

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered 'mmHg'	System	14 Oct 2020 16:56:27

US3322429

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20

US3322429

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20

US3322429

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:58:30

US3322429

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '14 Oct 2020'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 16:58:30

US3322429

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:07:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '14 Oct 2020'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:00:25

US3322429

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User closed query 'Per CDM: Please consider adding contraceptive method under CM form or clarify otherwise. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:39:08
Query 'Per CDM: Please consider adding contraceptive method under CM form or clarify otherwise. Thank you!' answered with 'Subject's contraception method is sterilization of monogamous male partner prior to entry into the study. ' (Site from DM).	Blessing Felix-Okoroji (b) (4)	22 Oct 2020 15:31:35
User opened query 'Per CDM: Please consider adding contraceptive method under CM form or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 12:31:43
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:00:25

US3322429

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:07:21

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:00:25

US3322429

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:07:21

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:00:25

US3322429

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:00:25

US3322429

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:07:21

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:00:25

US3322429

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:00:25

US3322429

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:07:21

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:00:25

US3322429

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:00:58

US3322429

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '14 Oct 2020'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:00:58

US3322429

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Urine (URINE)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:00:58

US3322429

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Negative (NEGATIVE)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:00:58

US3322429

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:00:58

US3322429

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:00:58

US3322429

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:00:58

US3322429

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered empty.	System	14 Oct 2020 17:00:58

US3322429

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:02

US3322429

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:02

US3322429

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:21

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:02

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Folder: Screening

Form: Risk of Exposure

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Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:02

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:02

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Folder: Screening

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:02

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Folder: Screening

Form: Risk of Exposure

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Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:02

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Folder: Screening

Form: Risk of Exposure

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Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:02

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Folder: Screening

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Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:02

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Folder: Screening

Form: Risk of Exposure

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Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:02

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Folder: Screening

Form: Risk of Exposure

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:02

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:02

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Director Food Service sale .'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:02

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Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:02

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:02

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Folder: Screening

Form: Risk of Exposure

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:02

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:21

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:02

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:21

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:02

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:02

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:21

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'I'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:02

US3322429

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '-Works Outside home>2/week, contact >5/day . -Children goes to school/daycare in person - Attends Gathering of 10 PPI 2/month (2) DInes in 1/week Gym 2/week.'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:02

US3322429

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:07:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:25

US3322429

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '14 Oct 2020'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:25

US3322429

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Clinic (Clinic)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:25

US3322429

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:07:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'VISIT1'	System	14 Oct 2020 17:02:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '14 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Oct 2020 15:38:46

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '117065'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Oct 2020 15:38:46

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Oct 2020 15:38:46

US3322429

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:21

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)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:38

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:21

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)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:38

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:38

US3322429

Folder: Visit 1 Day 1

Form: Randomization

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Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:38

US3322429

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:21

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:02:38

US3322429

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji	14 Oct 2020 17:02:38
DataPoint set to visible.	(b) (4) System	14 Oct 2020 16:04:44

US3322429

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:21

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered missing code ND - Not Done.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

US3322429

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered missing code ND - Not Done.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

US3322429

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:21

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered missing code ND - Not Done.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

US3322429

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered missing code ND - Not Done.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User accepted default value 'Pre-Dose (PREDOSE)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

US3322429

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '14 Oct 2020'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '09:29'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered '14 Oct 2020 09:29'	System	14 Oct 2020 17:06:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '97.4' F	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Oral (Oral)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

US3322429

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '65'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'bpm'	System	14 Oct 2020 17:06:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '15'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'breaths/min'	System	14 Oct 2020 17:06:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '112'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'mmHg'	System	14 Oct 2020 17:06:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '64'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'mmHg'	System	14 Oct 2020 17:06:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:21

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered missing code ND - Not Done.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

US3322429

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered missing code ND - Not Done.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User accepted default value 'Post-Dose (POSTDOSE)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

US3322429

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '14 Oct 2020'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

US3322429

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '11:34'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

US3322429

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered '14 Oct 2020 11:34'	System	14 Oct 2020 17:06:19

US3322429

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '97.9' F	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

US3322429

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Oral (Oral)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

US3322429

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

US3322429

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '67'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

US3322429

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'bpm'	System	14 Oct 2020 17:06:19

US3322429

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '15'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

US3322429

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'breaths/min'	System	14 Oct 2020 17:06:19

US3322429

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '97'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

US3322429

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'mmHg'	System	14 Oct 2020 17:06:19

US3322429

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
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)	15 Oct 2020 09:00:19
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 'Per doctor's progress note in source, this is NCS. Subject was asymptomatic and reported that diastolic has been in the 50s without incident.' (Site from System).	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 18:25:55
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).		14 Oct 2020 17:06:19
User entered '54'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:06:19

US3322429

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'mmHg'	System	14 Oct 2020 17:06:19

US3322429

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:19:25

US3322429

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:19:25

US3322429

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:19:32

US3322429

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:19:32

US3322429

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:19:32

US3322429

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:19:32

US3322429

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:19:32

US3322429

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:19:32

US3322429

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:19:32

US3322429

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered empty.	System	14 Oct 2020 17:19:32

US3322429

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Frances Saubon (b) (4)	14 Oct 2020 16:05:07

US3322429

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:21

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Frances Saubon (b) (4)	14 Oct 2020 16:05:07

US3322429

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Frances Saubon (b) (4)	14 Oct 2020 16:05:07

US3322429

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'MRNA-1273 OR PLACEBO'	System	14 Oct 2020 16:05:07

US3322429

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '14 Oct 2020'	Frances Saubon (b) (4)	14 Oct 2020 16:05:07

US3322429

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '10:57'	Frances Saubon (b) (4)	14 Oct 2020 16:05:07

US3322429

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered '14 Oct 2020 10:57'	System	14 Oct 2020 16:05:07

US3322429

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Left Arm (LEFT ARM)'	Frances Saubon (b) (4)	14 Oct 2020 16:05:07

US3322429

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'ONCE'	System	14 Oct 2020 16:05:07

US3322429

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'INTRAMUSCULAR'	System	14 Oct 2020 16:05:07

US3322429

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:20:37

US3322429

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '14 Oct 2020'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:20:37

US3322429

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '10:40'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:20:37

US3322429

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered '14 Oct 2020 10:40'	System	14 Oct 2020 17:20:37

US3322429

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:07:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '14 Oct 2020'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:21:06

US3322429

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:21:06

US3322429

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:21:06

US3322429

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '10:37'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:21:06

US3322429

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:21

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered '14 Oct 2020 10:37'	System	14 Oct 2020 17:21:06

US3322429

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:21:06

US3322429

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:21:06

US3322429

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:21:06

US3322429

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:21

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered empty.	System	14 Oct 2020 17:21:06

US3322429

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:21:16

US3322429

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'I'	System	14 Oct 2020 17:21:16

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T11:34:23', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '019f347c-1000-40f4-b4f1-d35560d91475' User entered 'Yes (Y)'	System	14 Oct 2020 16:34:38
	System	14 Oct 2020 16:34:38

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T11:34:26', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '019f347c-1000-40f4-b4f1-d35560d91475' User entered '97.9'	System	14 Oct 2020 16:34:38
	System	14 Oct 2020 16:34:38

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T11:34:30', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '019f347c-1000-40f4-b4f1-d35560d91475'	System	14 Oct 2020 16:34:38
User entered 'No (N)'	System	14 Oct 2020 16:34:38

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T11:34:34', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '019f347c-1000-40f4-b4f1-d35560d91475' User entered '14 Oct 2020 11:34'	System	14 Oct 2020 16:34:38
	System	14 Oct 2020 16:34:38

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '14 Oct 2020 11:17'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '14 Oct 2020 13:47'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T21:05:51', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'a5cabd88-33f3-4164-af3a-0c221a64a847'	System	15 Oct 2020 02:06:05
User entered 'Yes (Y)'	System	15 Oct 2020 02:06:05

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T21:05:55', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'a5cabd88-33f3-4164-af3a-0c221a64a847'	System	15 Oct 2020 02:06:05
User entered '98.6'	System	15 Oct 2020 02:06:05

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T21:05:58', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'a5cabd88-33f3-4164-af3a-0c221a64a847'	System	15 Oct 2020 02:06:05
User entered 'No (N)'	System	15 Oct 2020 02:06:05

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T21:06:01', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'a5cabd88-33f3-4164-af3a-0c221a64a847'	System	15 Oct 2020 02:06:05
User entered '14 Oct 2020 21:06'	System	15 Oct 2020 02:06:05

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '14 Oct 2020 14:42'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 2'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-15T20:17:49', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'f9316c88-fe89-4502-9146-885616e6c4da' User entered 'Yes (Y)'	System	16 Oct 2020 01:18:05
	System	16 Oct 2020 01:18:05

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-15T20:17:53', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'f9316c88-fe89-4502-9146-885616e6c4da' User entered '97.7'	System	16 Oct 2020 01:18:05
	System	16 Oct 2020 01:18:05

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-15T20:17:56', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'f9316c88-fe89-4502-9146-885616e6c4da' User entered 'No (N)'	System	16 Oct 2020 01:18:05
	System	16 Oct 2020 01:18:05

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-15T20:17:59', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'f9316c88-fe89-4502-9146-885616e6c4da' User entered '15 Oct 2020 20:17'	System	16 Oct 2020 01:18:05
	System	16 Oct 2020 01:18:05

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 3'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-16T22:13:40', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '7f7a509c-c722-4076-a824-efaa362ad7cc' User entered 'Yes (Y)'	System	17 Oct 2020 03:13:55
	System	17 Oct 2020 03:13:55

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-16T22:13:45', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '7f7a509c-c722-4076-a824-efaa362ad7cc' User entered '97.9'	System	17 Oct 2020 03:13:55
	System	17 Oct 2020 03:13:55

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-16T22:13:48', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '7f7a509c-c722-4076-a824-efaa362ad7cc' User entered 'No (N)'	System	17 Oct 2020 03:13:55
	System	17 Oct 2020 03:13:55

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-16T22:13:51', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '7f7a509c-c722-4076-a824-efaa362ad7cc' User entered '16 Oct 2020 22:13'	System	17 Oct 2020 03:13:55
	System	17 Oct 2020 03:13:55

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 4'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-17T22:45:47', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '842ff7c2-db27-43fd-b305-20c0ac572c4b' User entered 'Yes (Y)'	System	18 Oct 2020 03:46:01
	System	18 Oct 2020 03:46:01

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-17T22:45:53', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '842ff7c2-db27-43fd-b305-20c0ac572c4b' User entered '98.2'	System	18 Oct 2020 03:46:01
	System	18 Oct 2020 03:46:01

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-17T22:45:55', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '842ff7c2-db27-43fd-b305-20c0ac572c4b' User entered 'No (N)'	System	18 Oct 2020 03:46:01
	System	18 Oct 2020 03:46:01

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-17T22:45:58', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '842ff7c2-db27-43fd-b305-20c0ac572c4b' User entered '17 Oct 2020 22:45'	System	18 Oct 2020 03:46:01
	System	18 Oct 2020 03:46:01

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 5'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-18T21:58:34', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '4628cc8a-dcd1-450e-8f5f-e56ef7d2b21e' User entered 'Yes (Y)'	System	19 Oct 2020 02:58:49
	System	19 Oct 2020 02:58:49

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-18T21:58:43', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '4628cc8a-dcd1-450e-8f5f-e56ef7d2b21e' User entered '97.5'	System	19 Oct 2020 02:58:49
	System	19 Oct 2020 02:58:49

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-18T21:58:45', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '4628cc8a-dcd1-450e-8f5f-e56ef7d2b21e' User entered 'No (N)'	System	19 Oct 2020 02:58:49
	System	19 Oct 2020 02:58:49

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-18T21:58:48', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '4628cc8a-dcd1-450e-8f5f-e56ef7d2b21e' User entered '18 Oct 2020 21:58'	System	19 Oct 2020 02:58:49
	System	19 Oct 2020 02:58:49

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 6'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-19T20:43:04', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '54736ee0-de7d-495d-84e9-e67de6d42470' User entered 'Yes (Y)'	System	20 Oct 2020 01:43:15
	System	20 Oct 2020 01:43:15

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-19T20:43:07', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '54736ee0-de7d-495d-84e9-e67de6d42470' User entered '98.1'	System	20 Oct 2020 01:43:15
	System	20 Oct 2020 01:43:15

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-19T20:43:10', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '54736ee0-de7d-495d-84e9-e67de6d42470' User entered 'No (N)'	System	20 Oct 2020 01:43:15
	System	20 Oct 2020 01:43:15

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-19T20:43:12', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '54736ee0-de7d-495d-84e9-e67de6d42470' User entered '19 Oct 2020 20:43'	System	20 Oct 2020 01:43:15
	System	20 Oct 2020 01:43:15

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 7'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-20T20:39:32', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '7cdac31a-f084-418c-b8fb-2ec036d2572b' User entered 'Yes (Y)'	System	21 Oct 2020 01:39:43
	System	21 Oct 2020 01:39:43

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-20T20:39:34', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '7cdac31a-f084-418c-b8fb-2ec036d2572b' User entered '98.1'	System	21 Oct 2020 01:39:43
	System	21 Oct 2020 01:39:43

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-20T20:39:37', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '7cdac31a-f084-418c-b8fb-2ec036d2572b' User entered 'No (N)'	System	21 Oct 2020 01:39:43
	System	21 Oct 2020 01:39:43

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-20T20:39:40', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '7cdac31a-f084-418c-b8fb-2ec036d2572b' User entered '20 Oct 2020 20:39'	System	21 Oct 2020 01:39:43
	System	21 Oct 2020 01:39:43

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T11:34:50', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'c4a28aa4-c566-4292-807f-c86a4f2180c7' User entered 'None (1)'	System	14 Oct 2020 16:35:08
	System	14 Oct 2020 16:35:08

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T11:34:53', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'c4a28aa4-c566-4292-807f-c86a4f2180c7' User entered 'No (N)'	System	14 Oct 2020 16:35:08
	System	14 Oct 2020 16:35:08

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T11:34:55', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'c4a28aa4-c566-4292-807f-c86a4f2180c7' User entered 'No (N)'	System	14 Oct 2020 16:35:08
	System	14 Oct 2020 16:35:08

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T11:34:58', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'c4a28aa4-c566-4292-807f-c86a4f2180c7' User entered 'None (1)'	System	14 Oct 2020 16:35:08
	System	14 Oct 2020 16:35:08

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T11:35:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'c4a28aa4-c566-4292-807f-c86a4f2180c7' User entered '14 Oct 2020 11:35'	System	14 Oct 2020 16:35:08
	System	14 Oct 2020 16:35:08

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '14 Oct 2020 11:17'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '14 Oct 2020 13:47'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T21:04:16', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '82823d91-0520-475c-9a1e-93dcaa914630'	System	15 Oct 2020 02:05:46
User entered 'Does not interfere with activity (2)'	System	15 Oct 2020 02:05:46

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T21:04:19', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '82823d91-0520-475c-9a1e-93dcaa914630' User entered 'No (N)'	System	15 Oct 2020 02:05:46
	System	15 Oct 2020 02:05:46

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T21:04:21', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '82823d91-0520-475c-9a1e-93dcaa914630' User entered 'Yes (Y)'	System	15 Oct 2020 02:05:46
	System	15 Oct 2020 02:05:46

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T21:05:20', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '82823d91-0520-475c-9a1e-93dcaa914630' User entered '2'	System	15 Oct 2020 02:05:46
	System	15 Oct 2020 02:05:46

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T21:05:27', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '82823d91-0520-475c-9a1e-93dcaa914630' User entered 'None (1)'	System	15 Oct 2020 02:05:46
	System	15 Oct 2020 02:05:46

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T21:05:43', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '82823d91-0520-475c-9a1e-93dcaa914630' User entered '14 Oct 2020 21:05'	System	15 Oct 2020 02:05:46
	System	15 Oct 2020 02:05:46

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '14 Oct 2020 14:42'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 2'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-15T20:20:26', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b0801b4b-6c90-43ca-a9d2-8b4b0c451dc6'	System	16 Oct 2020 01:21:11
User entered 'Does not interfere with activity (2)'	System	16 Oct 2020 01:21:11

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-15T20:20:29', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b0801b4b-6c90-43ca-a9d2-8b4b0c451dc6' User entered 'No (N)'	System	16 Oct 2020 01:21:11
	System	16 Oct 2020 01:21:11

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-15T20:20:31', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b0801b4b-6c90-43ca-a9d2-8b4b0c451dc6' User entered 'Yes (Y)'	System	16 Oct 2020 01:21:11
	System	16 Oct 2020 01:21:11

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-15T20:20:59', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b0801b4b-6c90-43ca-a9d2-8b4b0c451dc6' User entered '1'	System	16 Oct 2020 01:21:11
	System	16 Oct 2020 01:21:11

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-15T20:21:03', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b0801b4b-6c90-43ca-a9d2-8b4b0c451dc6' User entered 'None (1)'	System	16 Oct 2020 01:21:11
	System	16 Oct 2020 01:21:11

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-15T20:21:07', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b0801b4b-6c90-43ca-a9d2-8b4b0c451dc6' User entered '15 Oct 2020 20:21'	System	16 Oct 2020 01:21:11
	System	16 Oct 2020 01:21:11

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 3'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-16T22:14:02', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd3b32f1c-6c9b-4ee1-8fee-efc6ba6c1ffc'	System	17 Oct 2020 03:14:15
User entered 'None (1)'	System	17 Oct 2020 03:14:15

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-16T22:14:05', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd3b32f1c-6c9b-4ee1-8fee-efc6ba6c1ffc'	System	17 Oct 2020 03:14:15
User entered 'No (N)'	System	17 Oct 2020 03:14:15

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-16T22:14:07', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd3b32f1c-6c9b-4ee1-8fee-efc6ba6c1ffc'	System	17 Oct 2020 03:14:15
User entered 'No (N)'	System	17 Oct 2020 03:14:15

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-16T22:14:09', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd3b32f1c-6c9b-4ee1-8fee-efc6ba6c1ffc'	System	17 Oct 2020 03:14:15
User entered 'None (1)'	System	17 Oct 2020 03:14:15

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-16T22:14:12', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd3b32f1c-6c9b-4ee1-8fee-efc6ba6c1ffc' User entered '16 Oct 2020 22:14'	System	17 Oct 2020 03:14:15
	System	17 Oct 2020 03:14:15

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 4'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-17T22:46:02', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '020eb935-4b93-4d42-b803-c5f7f6d3cb71' User entered 'None (1)'	System	18 Oct 2020 03:46:13
	System	18 Oct 2020 03:46:13

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-17T22:46:04', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '020eb935-4b93-4d42-b803-c5f7f6d3cb71' User entered 'No (N)'	System	18 Oct 2020 03:46:13
	System	18 Oct 2020 03:46:13

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-17T22:46:06', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '020eb935-4b93-4d42-b803-c5f7f6d3cb71' User entered 'No (N)'	System	18 Oct 2020 03:46:13
	System	18 Oct 2020 03:46:13

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-17T22:46:08', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '020eb935-4b93-4d42-b803-c5f7f6d3cb71' User entered 'None (1)'	System	18 Oct 2020 03:46:13
	System	18 Oct 2020 03:46:13

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-17T22:46:10', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '020eb935-4b93-4d42-b803-c5f7f6d3cb71' User entered '17 Oct 2020 22:46'	System	18 Oct 2020 03:46:13
	System	18 Oct 2020 03:46:13

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 5'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-18T21:58:51', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '4480199a-4eb6-43c2-aa84-2893c2280e50' User entered 'None (1)'	System	19 Oct 2020 02:59:00
	System	19 Oct 2020 02:59:00

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-18T21:58:53', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '4480199a-4eb6-43c2-aa84-2893c2280e50' User entered 'No (N)'	System	19 Oct 2020 02:59:00
	System	19 Oct 2020 02:59:00

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-18T21:58:54', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '4480199a-4eb6-43c2-aa84-2893c2280e50' User entered 'No (N)'	System	19 Oct 2020 02:59:00
	System	19 Oct 2020 02:59:00

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-18T21:58:56', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '4480199a-4eb6-43c2-aa84-2893c2280e50'	System	19 Oct 2020 02:59:00
User entered 'None (1)'	System	19 Oct 2020 02:59:00

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-18T21:58:58', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '4480199a-4eb6-43c2-aa84-2893c2280e50' User entered '18 Oct 2020 21:58'	System	19 Oct 2020 02:59:00
	System	19 Oct 2020 02:59:00

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 6'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-19T20:43:15', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8f680e53-1051-4a2e-820e-eb06bd3c5aad' User entered 'None (1)'	System	20 Oct 2020 01:43:26
	System	20 Oct 2020 01:43:26

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-19T20:43:17', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8f680e53-1051-4a2e-820e-eb06bd3c5aad' User entered 'No (N)'	System	20 Oct 2020 01:43:26
	System	20 Oct 2020 01:43:26

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-19T20:43:19', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8f680e53-1051-4a2e-820e-eb06bd3c5aad' User entered 'No (N)'	System	20 Oct 2020 01:43:26
	System	20 Oct 2020 01:43:26

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-19T20:43:20', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8f680e53-1051-4a2e-820e-eb06bd3c5aad' User entered 'None (1)'	System	20 Oct 2020 01:43:26
	System	20 Oct 2020 01:43:26

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-19T20:43:23', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8f680e53-1051-4a2e-820e-eb06bd3c5aad' User entered '19 Oct 2020 20:43'	System	20 Oct 2020 01:43:26
	System	20 Oct 2020 01:43:26

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 7'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-20T20:39:44', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'fc400fec-07c4-42ac-b76c-a101ff602eb3'	System	21 Oct 2020 01:39:56
User entered 'None (1)'	System	21 Oct 2020 01:39:56

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-20T20:39:46', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'fc400fec-07c4-42ac-b76c-a101ff602eb3'	System	21 Oct 2020 01:39:56
User entered 'No (N)'	System	21 Oct 2020 01:39:56

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-20T20:39:48', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'fc400fec-07c4-42ac-b76c-a101ff602eb3' User entered 'No (N)'	System	21 Oct 2020 01:39:56
	System	21 Oct 2020 01:39:56

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-20T20:39:50', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'fc400fec-07c4-42ac-b76c-a101ff602eb3'	System	21 Oct 2020 01:39:56
User entered 'None (1)'	System	21 Oct 2020 01:39:56

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-20T20:39:52', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'fc400fec-07c4-42ac-b76c-a101ff602eb3' User entered '20 Oct 2020 20:39'	System	21 Oct 2020 01:39:56
	System	21 Oct 2020 01:39:56

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T11:35:03', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '7bfb93f2-8bdd-4c63-ba96-2a934c4e34ca' User entered 'None (0)'	System	14 Oct 2020 16:35:18
	System	14 Oct 2020 16:35:18

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T11:35:05', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '7bfb93f2-8bdd-4c63-ba96-2a934c4e34ca' User entered 'None (0)'	System	14 Oct 2020 16:35:18
	System	14 Oct 2020 16:35:18

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T11:35:06', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '7bfb93f2-8bdd-4c63-ba96-2a934c4e34ca' User entered 'None (0)'	System	14 Oct 2020 16:35:18
	System	14 Oct 2020 16:35:18

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T11:35:08', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '7bfb93f2-8bdd-4c63-ba96-2a934c4e34ca' User entered 'None (0)'	System	14 Oct 2020 16:35:18
	System	14 Oct 2020 16:35:18

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T11:35:09', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '7bfb93f2-8bdd-4c63-ba96-2a934c4e34ca' User entered 'None (0)'	System	14 Oct 2020 16:35:18
	System	14 Oct 2020 16:35:18

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T11:35:11', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '7bfb93f2-8bdd-4c63-ba96-2a934c4e34ca' User entered 'None (0)'	System	14 Oct 2020 16:35:18
	System	14 Oct 2020 16:35:18

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

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)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T11:35:12', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '7bfb93f2-8bdd-4c63-ba96-2a934c4e34ca' User entered 'No (N)'	System	14 Oct 2020 16:35:18
	System	14 Oct 2020 16:35:18

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T11:35:15', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '7bfb93f2-8bdd-4c63-ba96-2a934c4e34ca' User entered '14 Oct 2020 11:35'	System	14 Oct 2020 16:35:18
	System	14 Oct 2020 16:35:18

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '14 Oct 2020 11:17'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '14 Oct 2020 13:47'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T21:06:05', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'a997f18d-5add-4797-92c0-a70cc4f12fe0' User entered 'None (0)'	System	15 Oct 2020 02:06:36
	System	15 Oct 2020 02:06:36

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T21:06:15', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'a997f18d-5add-4797-92c0-a70cc4f12fe0'	System	15 Oct 2020 02:06:36
User entered 'No interference with activity (1)'	System	15 Oct 2020 02:06:36

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T21:06:18', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'a997f18d-5add-4797-92c0-a70cc4f12fe0' User entered 'None (0)'	System	15 Oct 2020 02:06:36
	System	15 Oct 2020 02:06:36

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T21:06:21', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'a997f18d-5add-4797-92c0-a70cc4f12fe0' User entered 'None (0)'	System	15 Oct 2020 02:06:36
	System	15 Oct 2020 02:06:36

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T21:06:23', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'a997f18d-5add-4797-92c0-a70cc4f12fe0' User entered 'None (0)'	System	15 Oct 2020 02:06:36
	System	15 Oct 2020 02:06:36

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T21:06:24', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'a997f18d-5add-4797-92c0-a70cc4f12fe0' User entered 'None (0)'	System	15 Oct 2020 02:06:36
	System	15 Oct 2020 02:06:36

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

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)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T21:06:27', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'a997f18d-5add-4797-92c0-a70cc4f12fe0' User entered 'No (N)'	System	15 Oct 2020 02:06:36
	System	15 Oct 2020 02:06:36

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-14T21:06:32', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'a997f18d-5add-4797-92c0-a70cc4f12fe0' User entered '14 Oct 2020 21:06'	System	15 Oct 2020 02:06:36
	System	15 Oct 2020 02:06:36

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '14 Oct 2020 14:42'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 2'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-15T20:21:11', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '9587f8b7-4bcb-4826-9a8c-e80128ce5443' User entered 'None (0)'	System	16 Oct 2020 01:21:38
	System	16 Oct 2020 01:21:38

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-15T20:21:20', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '9587f8b7-4bcb-4826-9a8c-e80128ce5443'	System	16 Oct 2020 01:21:38
User entered 'No interference with activity (1)'	System	16 Oct 2020 01:21:38

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-15T20:21:23', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '9587f8b7-4bcb-4826-9a8c-e80128ce5443' User entered 'None (0)'	System	16 Oct 2020 01:21:38
	System	16 Oct 2020 01:21:38

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-15T20:21:25', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '9587f8b7-4bcb-4826-9a8c-e80128ce5443' User entered 'None (0)'	System	16 Oct 2020 01:21:38
	System	16 Oct 2020 01:21:38

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-15T20:21:27', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '9587f8b7-4bcb-4826-9a8c-e80128ce5443' User entered 'None (0)'	System	16 Oct 2020 01:21:38
	System	16 Oct 2020 01:21:38

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-15T20:21:30', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '9587f8b7-4bcb-4826-9a8c-e80128ce5443' User entered 'None (0)'	System	16 Oct 2020 01:21:38
	System	16 Oct 2020 01:21:38

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

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)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-15T20:21:32', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '9587f8b7-4bcb-4826-9a8c-e80128ce5443' User entered 'No (N)'	System	16 Oct 2020 01:21:38
	System	16 Oct 2020 01:21:38

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-15T20:21:35', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '9587f8b7-4bcb-4826-9a8c-e80128ce5443' User entered '15 Oct 2020 20:21'	System	16 Oct 2020 01:21:38
	System	16 Oct 2020 01:21:38

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 3'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-16T22:14:15', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '37f2c645-2871-41cf-a7b4-e4ee2a5e40d0' User entered 'None (0)'	System	17 Oct 2020 03:14:31
	System	17 Oct 2020 03:14:31

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-16T22:14:17', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '37f2c645-2871-41cf-a7b4-e4ee2a5e40d0' User entered 'None (0)'	System	17 Oct 2020 03:14:31
	System	17 Oct 2020 03:14:31

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-16T22:14:19', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '37f2c645-2871-41cf-a7b4-e4ee2a5e40d0' User entered 'None (0)'	System	17 Oct 2020 03:14:31
	System	17 Oct 2020 03:14:31

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-16T22:14:21', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '37f2c645-2871-41cf-a7b4-e4ee2a5e40d0' User entered 'None (0)'	System	17 Oct 2020 03:14:31
	System	17 Oct 2020 03:14:31

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-16T22:14:22', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '37f2c645-2871-41cf-a7b4-e4ee2a5e40d0' User entered 'None (0)'	System	17 Oct 2020 03:14:31
	System	17 Oct 2020 03:14:31

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-16T22:14:24', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '37f2c645-2871-41cf-a7b4-e4ee2a5e40d0' User entered 'None (0)'	System	17 Oct 2020 03:14:31
	System	17 Oct 2020 03:14:31

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

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)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-16T22:14:26', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '37f2c645-2871-41cf-a7b4-e4ee2a5e40d0' User entered 'No (N)'	System	17 Oct 2020 03:14:31
	System	17 Oct 2020 03:14:31

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-16T22:14:29', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '37f2c645-2871-41cf-a7b4-e4ee2a5e40d0' User entered '16 Oct 2020 22:14'	System	17 Oct 2020 03:14:31
	System	17 Oct 2020 03:14:31

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 4'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-17T22:46:13', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '2b5ccfa0-13d3-41bd-9ac0-a28b6f52d4b9' User entered 'None (0)'	System	18 Oct 2020 03:46:30
	System	18 Oct 2020 03:46:30

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-17T22:46:15', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '2b5ccfa0-13d3-41bd-9ac0-a28b6f52d4b9' User entered 'None (0)'	System	18 Oct 2020 03:46:30
	System	18 Oct 2020 03:46:30

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-17T22:46:16', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '2b5ccfa0-13d3-41bd-9ac0-a28b6f52d4b9' User entered 'None (0)'	System	18 Oct 2020 03:46:30
	System	18 Oct 2020 03:46:30

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-17T22:46:18', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '2b5ccfa0-13d3-41bd-9ac0-a28b6f52d4b9' User entered 'None (0)'	System	18 Oct 2020 03:46:30
	System	18 Oct 2020 03:46:30

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-17T22:46:19', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '2b5ccfa0-13d3-41bd-9ac0-a28b6f52d4b9' User entered 'None (0)'	System	18 Oct 2020 03:46:30
	System	18 Oct 2020 03:46:30

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-17T22:46:20', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '2b5ccfa0-13d3-41bd-9ac0-a28b6f52d4b9' User entered 'None (0)'	System	18 Oct 2020 03:46:30
	System	18 Oct 2020 03:46:30

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

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)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-17T22:46:22', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '2b5ccfa0-13d3-41bd-9ac0-a28b6f52d4b9' User entered 'No (N)'	System	18 Oct 2020 03:46:30
	System	18 Oct 2020 03:46:30

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-17T22:46:24', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '2b5ccfa0-13d3-41bd-9ac0-a28b6f52d4b9' User entered '17 Oct 2020 22:46'	System	18 Oct 2020 03:46:30
	System	18 Oct 2020 03:46:30

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 5'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-18T21:59:01', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'a67b9448-9941-4fc9-8756-7a9d4ab23aa8' User entered 'None (0)'	System	19 Oct 2020 02:59:14
	System	19 Oct 2020 02:59:14

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-18T21:59:02', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'a67b9448-9941-4fc9-8756-7a9d4ab23aa8' User entered 'None (0)'	System	19 Oct 2020 02:59:14
	System	19 Oct 2020 02:59:14

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-18T21:59:04', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'a67b9448-9941-4fc9-8756-7a9d4ab23aa8' User entered 'None (0)'	System	19 Oct 2020 02:59:14
	System	19 Oct 2020 02:59:14

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-18T21:59:05', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'a67b9448-9941-4fc9-8756-7a9d4ab23aa8' User entered 'None (0)'	System	19 Oct 2020 02:59:14
	System	19 Oct 2020 02:59:14

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-18T21:59:06', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'a67b9448-9941-4fc9-8756-7a9d4ab23aa8' User entered 'None (0)'	System	19 Oct 2020 02:59:14
	System	19 Oct 2020 02:59:14

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-18T21:59:08', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'a67b9448-9941-4fc9-8756-7a9d4ab23aa8' User entered 'None (0)'	System	19 Oct 2020 02:59:14
	System	19 Oct 2020 02:59:14

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

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)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-18T21:59:10', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'a67b9448-9941-4fc9-8756-7a9d4ab23aa8'	System	19 Oct 2020 02:59:14
User entered 'No (N)'	System	19 Oct 2020 02:59:14

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-18T21:59:12', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'a67b9448-9941-4fc9-8756-7a9d4ab23aa8' User entered '18 Oct 2020 21:59'	System	19 Oct 2020 02:59:14
	System	19 Oct 2020 02:59:14

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 6'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-19T20:43:28', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd1a669e4-2300-4cf1-b1bd-4eea5734036e' User entered 'None (0)'	System	20 Oct 2020 01:43:41
	System	20 Oct 2020 01:43:41

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-19T20:43:29', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd1a669e4-2300-4cf1-b1bd-4eea5734036e' User entered 'None (0)'	System	20 Oct 2020 01:43:41
	System	20 Oct 2020 01:43:41

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-19T20:43:30', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd1a669e4-2300-4cf1-b1bd-4eea5734036e' User entered 'None (0)'	System	20 Oct 2020 01:43:41
	System	20 Oct 2020 01:43:41

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-19T20:43:32', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd1a669e4-2300-4cf1-b1bd-4eea5734036e' User entered 'None (0)'	System	20 Oct 2020 01:43:41
	System	20 Oct 2020 01:43:41

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-19T20:43:33', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd1a669e4-2300-4cf1-b1bd-4eea5734036e' User entered 'None (0)'	System	20 Oct 2020 01:43:41
	System	20 Oct 2020 01:43:41

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-19T20:43:34', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd1a669e4-2300-4cf1-b1bd-4eea5734036e' User entered 'None (0)'	System	20 Oct 2020 01:43:41
	System	20 Oct 2020 01:43:41

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

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)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-19T20:43:36', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd1a669e4-2300-4cf1-b1bd-4eea5734036e' User entered 'No (N)'	System	20 Oct 2020 01:43:41
	System	20 Oct 2020 01:43:41

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-19T20:43:38', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd1a669e4-2300-4cf1-b1bd-4eea5734036e' User entered '19 Oct 2020 20:43'	System	20 Oct 2020 01:43:41
	System	20 Oct 2020 01:43:41

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
Data entry locked.	System	14 Oct 2020 16:05:07
User entered 'Day 7'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-20T20:39:55', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '4e1b3c5e-2dc5-4a1c-b663-529d2fcb2884' User entered 'None (0)'	System	21 Oct 2020 01:40:08
	System	21 Oct 2020 01:40:08

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-20T20:39:56', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '4e1b3c5e-2dc5-4a1c-b663-529d2fcb2884' User entered 'None (0)'	System	21 Oct 2020 01:40:08
	System	21 Oct 2020 01:40:08

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-20T20:39:58', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '4e1b3c5e-2dc5-4a1c-b663-529d2fcb2884' User entered 'None (0)'	System	21 Oct 2020 01:40:08
	System	21 Oct 2020 01:40:08

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-20T20:39:59', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '4e1b3c5e-2dc5-4a1c-b663-529d2fcb2884' User entered 'None (0)'	System	21 Oct 2020 01:40:08
	System	21 Oct 2020 01:40:08

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-20T20:40:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '4e1b3c5e-2dc5-4a1c-b663-529d2fcb2884' User entered 'None (0)'	System	21 Oct 2020 01:40:08
	System	21 Oct 2020 01:40:08

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-20T20:40:02', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '4e1b3c5e-2dc5-4a1c-b663-529d2fcb2884' User entered 'None (0)'	System	21 Oct 2020 01:40:08
	System	21 Oct 2020 01:40:08

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

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)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-20T20:40:03', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '4e1b3c5e-2dc5-4a1c-b663-529d2fcb2884' User entered 'No (N)'	System	21 Oct 2020 01:40:08
	System	21 Oct 2020 01:40:08

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-10-20T20:40:06', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '4e1b3c5e-2dc5-4a1c-b663-529d2fcb2884' User entered '20 Oct 2020 20:40'	System	21 Oct 2020 01:40:08
	System	21 Oct 2020 01:40:08

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 16:05:07

US3322429

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:22:03
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 16:05:07

US3322429

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	23 Oct 2020 14:04:58

US3322429

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '21 Oct 2020'	Elisa Moralez (b) (4)	23 Oct 2020 14:04:58

US3322429

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	23 Oct 2020 14:04:58

US3322429

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	23 Oct 2020 14:04:58

US3322429

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	23 Oct 2020 14:07:13

US3322429

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'I'	System	23 Oct 2020 14:07:13

US3322429

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	29 Oct 2020 15:02:14

US3322429

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '28 Oct 2020'	Elisa Moralez (b) (4)	29 Oct 2020 15:02:14

US3322429

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	29 Oct 2020 15:02:14

US3322429

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	29 Oct 2020 15:02:14

US3322429

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	29 Oct 2020 15:02:17

US3322429

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'I'	System	29 Oct 2020 15:02:17

US3322429

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	05 Nov 2020 18:22:08

US3322429

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '4 Nov 2020'	Elisa Moralez (b) (4)	05 Nov 2020 18:22:08

US3322429

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	05 Nov 2020 18:22:08

US3322429

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	05 Nov 2020 18:22:08

US3322429

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	05 Nov 2020 18:21:58

US3322429

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'I'	System	05 Nov 2020 18:21:58

US3322429

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Moez Talpur (b) (4)	10 Nov 2020 19:00:12

US3322429

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '10 Nov 2020'	Moez Talpur (b) (4)	10 Nov 2020 19:00:12

US3322429

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Clinic (Clinic)'	Moez Talpur (b) (4)	10 Nov 2020 19:00:12

US3322429

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'VISIT2'	System	10 Nov 2020 19:00:12

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User accepted default value 'Pre-Dose (PREDOSE)'	Moez Talpur (b) (4) (b) (4)	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Moez Talpur (b) (4)	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '10 Nov 2020'	Moez Talpur (b) (4)	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '10:38'	Moez Talpur (b) (4)	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered '10 Nov 2020 10:38'	System	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '97.7' F	Moez Talpur (b) (4)	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Oral (Oral)'	Moez Talpur (b) (4)	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Moez Talpur (b) (4)	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '84'	Moez Talpur (b) (4)	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'bpm'	System	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '13'	Moez Talpur (b) (4)	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'breaths/min'	System	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '130'	Moez Talpur (b) (4)	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'mmHg'	System	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '76'	Moez Talpur (b) (4)	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'mmHg'	System	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User accepted default value 'Post-Dose (POSTDOSE)'	Moez Talpur (b) (4) (b) (4)	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Moez Talpur (b) (4)	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '10 Nov 2020'	Moez Talpur (b) (4)	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '12:29'	Moez Talpur (b) (4)	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered '10 Nov 2020 12:29'	System	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:59:33
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per source' (Site from System).	Frances Saubon (b) (4) (b) (4)	11 Nov 2020 16:45:46
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	10 Nov 2020 19:02:02
User entered '96.1' F	Moez Talpur (b) (4) (b) (4)	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Oral (Oral)'	Moez Talpur (b) (4)	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Moez Talpur (b) (4)	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '79'	Moez Talpur (b) (4)	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'bpm'	System	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '13'	Moez Talpur (b) (4)	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'breaths/min'	System	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '117'	Moez Talpur (b) (4)	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'mmHg'	System	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '69'	Moez Talpur (b) (4)	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'mmHg'	System	10 Nov 2020 19:02:02

US3322429

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Moez Talpur (b) (4)	10 Nov 2020 19:04:41

US3322429

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '10 Nov 2020'	Moez Talpur (b) (4)	10 Nov 2020 19:04:41

US3322429

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Moez Talpur (b) (4)	10 Nov 2020 19:05:31

US3322429

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '10 Nov 2020'	Moez Talpur (b) (4)	10 Nov 2020 19:05:31

US3322429

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Urine (URINE)'	Moez Talpur (b) (4)	10 Nov 2020 19:05:31

US3322429

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Negative (NEGATIVE)'	Moez Talpur (b) (4)	10 Nov 2020 19:05:31

US3322429

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Moez Talpur (b) (4)	10 Nov 2020 19:05:31

US3322429

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Moez Talpur (b) (4)	10 Nov 2020 19:05:31

US3322429

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Moez Talpur (b) (4)	10 Nov 2020 19:05:31

US3322429

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:07:21

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered empty.	System	10 Nov 2020 19:05:31

US3322429

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Frances Saubon (b) (4)	10 Nov 2020 18:10:23

US3322429

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:21

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Frances Saubon (b) (4)	10 Nov 2020 18:10:23

US3322429

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Frances Saubon (b) (4)	10 Nov 2020 18:10:23

US3322429

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'MRNA-1273 OR PLACEBO'	System	10 Nov 2020 18:10:23

US3322429

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '10 Nov 2020'	Frances Saubon (b) (4)	10 Nov 2020 18:10:23

US3322429

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '12:08'	Frances Saubon (b) (4)	10 Nov 2020 18:10:23

US3322429

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered '10 Nov 2020 12:08'	System	10 Nov 2020 18:10:23

US3322429

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Left Arm (LEFT ARM)'	Frances Saubon (b) (4)	10 Nov 2020 18:10:23

US3322429

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'ONCE'	System	10 Nov 2020 18:10:23

US3322429

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'INTRAMUSCULAR'	System	10 Nov 2020 18:10:23

US3322429

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Moez Talpur (b) (4)	10 Nov 2020 19:05:55

US3322429

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '10 Nov 2020'	Moez Talpur (b) (4)	10 Nov 2020 19:05:55

US3322429

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '11:08'	Moez Talpur (b) (4)	10 Nov 2020 19:05:55

US3322429

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered '10 Nov 2020 11:08'	System	10 Nov 2020 19:05:55

US3322429

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:07:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '10 Nov 2020'	Moez Talpur (b) (4)	10 Nov 2020 19:06:16

US3322429

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Moez Talpur (b) (4) (b) (4)	10 Nov 2020 19:06:16

US3322429

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Moez Talpur (b) (4)	10 Nov 2020 19:06:16

US3322429

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '11:05'	Moez Talpur (b) (4)	10 Nov 2020 19:06:16

US3322429

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered '10 Nov 2020 11:05'	System	10 Nov 2020 19:06:16

US3322429

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Moez Talpur (b) (4) (b) (4)	10 Nov 2020 19:06:16

US3322429

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Moez Talpur (b) (4)	10 Nov 2020 19:06:16

US3322429

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Moez Talpur (b) (4)	10 Nov 2020 19:06:16

US3322429

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered empty.	System	10 Nov 2020 19:06:16

US3322429

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Moez Talpur (b) (4)	10 Nov 2020 19:06:21

US3322429

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'I'	System	10 Nov 2020 19:06:21

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T12:29:42', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '7f3827d6-1fa4-429e-bdb1-85e36c6d0841' User entered 'Yes (Y)'	System	10 Nov 2020 18:30:07
	System	10 Nov 2020 18:30:07

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T12:29:51', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '7f3827d6-1fa4-429e-bdb1-85e36c6d0841' User entered '96.1'	System	10 Nov 2020 18:30:07
	System	10 Nov 2020 18:30:07

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T12:29:54', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '7f3827d6-1fa4-429e-bdb1-85e36c6d0841' User entered 'No (N)'	System	10 Nov 2020 18:30:07
	System	10 Nov 2020 18:30:07

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T12:29:59', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '7f3827d6-1fa4-429e-bdb1-85e36c6d0841' User entered '10 Nov 2020 12:29'	System	10 Nov 2020 18:30:07
	System	10 Nov 2020 18:30:07

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '10 Nov 2020 12:28'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '10 Nov 2020 14:58'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 1, after vaccination (at home)'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T20:44:40', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'da640310-c68a-48fb-be82-98bd532353f7' User entered 'Yes (Y)'	System	11 Nov 2020 02:44:54
	System	11 Nov 2020 02:44:54

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T20:44:44', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'da640310-c68a-48fb-be82-98bd532353f7' User entered '98.1'	System	11 Nov 2020 02:44:54
	System	11 Nov 2020 02:44:54

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T20:44:46', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'da640310-c68a-48fb-be82-98bd532353f7' User entered 'No (N)'	System	11 Nov 2020 02:44:54
	System	11 Nov 2020 02:44:54

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T20:44:52', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'da640310-c68a-48fb-be82-98bd532353f7' User entered '10 Nov 2020 20:44'	System	11 Nov 2020 02:44:54
	System	11 Nov 2020 02:44:54

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '10 Nov 2020 15:53'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '11 Nov 2020 11:59'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 2'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-11T17:03:12', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '041d87f9-401e-48f3-b8d9-7a0bc11ea61b' User entered 'Yes (Y)'	System	11 Nov 2020 23:03:27
	System	11 Nov 2020 23:03:27

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-11T17:03:16', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '041d87f9-401e-48f3-b8d9-7a0bc11ea61b' User entered '100.0'	System	11 Nov 2020 23:03:27
	System	11 Nov 2020 23:03:27

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-11T17:03:19', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '041d87f9-401e-48f3-b8d9-7a0bc11ea61b' User entered 'No (N)'	System	11 Nov 2020 23:03:27
	System	11 Nov 2020 23:03:27

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-11T17:03:24', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '041d87f9-401e-48f3-b8d9-7a0bc11ea61b' User entered '11 Nov 2020 17:03'	System	11 Nov 2020 23:03:27
	System	11 Nov 2020 23:03:27

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '11 Nov 2020 12:00'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '12 Nov 2020 11:59'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 3'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-12T16:50:53', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e5987777-bd24-46c9-8049-2c51ccd9e210' User entered 'Yes (Y)'	System	12 Nov 2020 22:51:31
	System	12 Nov 2020 22:51:31

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-12T16:51:15', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e5987777-bd24-46c9-8049-2c51ccd9e210' User entered '97.4'	System	12 Nov 2020 22:51:31
	System	12 Nov 2020 22:51:31

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-12T16:51:20', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e5987777-bd24-46c9-8049-2c51ccd9e210'	System	12 Nov 2020 22:51:31
User entered 'Yes (Y)'	System	12 Nov 2020 22:51:31

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'patient has been followed up with please see updated conmeds' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 15:35:49
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-12T16:51:25', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e5987777-bd24-46c9-8049-2c51ccd9e210' User entered '1'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 15:19:10
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	12 Nov 2020 22:51:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-12T16:51:25', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e5987777-bd24-46c9-8049-2c51ccd9e210' User entered '1'	System	12 Nov 2020 22:51:31
User entered '1'	System	12 Nov 2020 22:51:31

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-12T16:51:25', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e5987777-bd24-46c9-8049-2c51ccd9e210' User entered '0'	System	12 Nov 2020 22:51:31
	System	12 Nov 2020 22:51:31

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-12T16:51:29', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e5987777-bd24-46c9-8049-2c51ccd9e210'	System	12 Nov 2020 22:51:31
User entered '12 Nov 2020 16:51'	System	12 Nov 2020 22:51:31

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '12 Nov 2020 12:00'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '13 Nov 2020 11:59'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 4'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-13T19:24:25', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e9ad6ec2-8a0d-4a91-9864-b691d1cd405b' User entered 'Yes (Y)'	System	14 Nov 2020 01:25:01
	System	14 Nov 2020 01:25:01

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-13T19:24:50', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e9ad6ec2-8a0d-4a91-9864-b691d1cd405b' User entered '97.2'	System	14 Nov 2020 01:25:01
	System	14 Nov 2020 01:25:01

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-13T19:24:53', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e9ad6ec2-8a0d-4a91-9864-b691d1cd405b' User entered 'No (N)'	System	14 Nov 2020 01:25:01
	System	14 Nov 2020 01:25:01

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-13T19:24:57', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e9ad6ec2-8a0d-4a91-9864-b691d1cd405b' User entered '13 Nov 2020 19:24'	System	14 Nov 2020 01:25:01
	System	14 Nov 2020 01:25:01

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '13 Nov 2020 12:00'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '14 Nov 2020 11:59'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 5'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-14T21:42:30', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '146c4972-1cfa-4419-8141-2b3fb03bb937'	System	15 Nov 2020 03:42:45
User entered 'Yes (Y)'	System	15 Nov 2020 03:42:45

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-14T21:42:33', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '146c4972-1cfa-4419-8141-2b3fb03bb937' User entered '97.8'	System	15 Nov 2020 03:42:45
	System	15 Nov 2020 03:42:45

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-14T21:42:36', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '146c4972-1cfa-4419-8141-2b3fb03bb937'	System	15 Nov 2020 03:42:45
User entered 'No (N)'	System	15 Nov 2020 03:42:45

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-14T21:42:42', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '146c4972-1cfa-4419-8141-2b3fb03bb937'	System	15 Nov 2020 03:42:45
User entered '14 Nov 2020 21:42'	System	15 Nov 2020 03:42:45

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '14 Nov 2020 12:00'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '15 Nov 2020 11:59'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 6'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-15T21:24:17', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '476fc0ee-993c-42c1-832f-9197f85a05af' User entered 'Yes (Y)'	System	16 Nov 2020 03:24:29
	System	16 Nov 2020 03:24:29

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-15T21:24:20', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '476fc0ee-993c-42c1-832f-9197f85a05af' User entered '97.8'	System	16 Nov 2020 03:24:29
	System	16 Nov 2020 03:24:29

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-15T21:24:23', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '476fc0ee-993c-42c1-832f-9197f85a05af' User entered 'No (N)'	System	16 Nov 2020 03:24:29
	System	16 Nov 2020 03:24:29

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-15T21:24:26', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '476fc0ee-993c-42c1-832f-9197f85a05af' User entered '15 Nov 2020 21:24'	System	16 Nov 2020 03:24:29
	System	16 Nov 2020 03:24:29

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '15 Nov 2020 12:00'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '16 Nov 2020 11:59'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 7'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-16T21:07:59', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '00c78fae-4753-46a3-9dad-bfce8212a581' User entered 'Yes (Y)'	System	17 Nov 2020 03:09:13
	System	17 Nov 2020 03:09:13

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-16T21:08:59', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '00c78fae-4753-46a3-9dad-bfce8212a581' User entered '96.9'	System	17 Nov 2020 03:09:13
	System	17 Nov 2020 03:09:13

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-16T21:09:01', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '00c78fae-4753-46a3-9dad-bfce8212a581' User entered 'No (N)'	System	17 Nov 2020 03:09:13
	System	17 Nov 2020 03:09:13

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-16T21:09:10', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '00c78fae-4753-46a3-9dad-bfce8212a581' User entered '16 Nov 2020 21:09'	System	17 Nov 2020 03:09:13
	System	17 Nov 2020 03:09:13

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '16 Nov 2020 12:00'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '17 Nov 2020 11:59'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T12:30:03', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'fa7c1ce7-ea9c-4267-abeb-0e01aae8dfb8' User entered 'None (1)'	System	10 Nov 2020 18:30:36
	System	10 Nov 2020 18:30:36

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T12:30:24', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'fa7c1ce7-ea9c-4267-abeb-0e01aae8dfb8' User entered 'No (N)'	System	10 Nov 2020 18:30:36
	System	10 Nov 2020 18:30:36

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T12:30:26', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'fa7c1ce7-ea9c-4267-abe01aae8dfb8'	System	10 Nov 2020 18:30:36
User entered 'No (N)'	System	10 Nov 2020 18:30:36

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T12:30:29', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'fa7c1ce7-ea9c-4267-abeb-0e01aae8dfb8' User entered 'None (1)'	System	10 Nov 2020 18:30:36
	System	10 Nov 2020 18:30:36

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T12:30:33', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'fa7c1ce7-ea9c-4267-abe8-0e01aae8dfb8' User entered '10 Nov 2020 12:30'	System	10 Nov 2020 18:30:36
	System	10 Nov 2020 18:30:36

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '10 Nov 2020 12:28'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '10 Nov 2020 14:58'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 1, after vaccination (at home)'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T20:44:56', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '2c674d5a-c9c3-438b-8d1b-c7b0ce7dd38d' User entered 'Does not interfere with activity (2)'	System	11 Nov 2020 02:47:48
	System	11 Nov 2020 02:47:48

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T20:45:28', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '2c674d5a-c9c3-438b-8d1b-c7b0ce7dd38d' User entered 'Yes (Y)'	System	11 Nov 2020 02:47:48
	System	11 Nov 2020 02:47:48

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T20:47:24', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '2c674d5a-c9c3-438b-8d1b-c7b0ce7dd38d' User entered '20'	System	11 Nov 2020 02:47:48
	System	11 Nov 2020 02:47:48

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T20:47:27', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '2c674d5a-c9c3-438b-8d1b-c7b0ce7dd38d' User entered 'Yes (Y)'	System	11 Nov 2020 02:47:48
	System	11 Nov 2020 02:47:48

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T20:47:33', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '2c674d5a-c9c3-438b-8d1b-c7b0ce7dd38d' User entered '20'	System	11 Nov 2020 02:47:48
	System	11 Nov 2020 02:47:48

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T20:47:41', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '2c674d5a-c9c3-438b-8d1b-c7b0ce7dd38d' User entered 'None (1)'	System	11 Nov 2020 02:47:48
	System	11 Nov 2020 02:47:48

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T20:47:46', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '2c674d5a-c9c3-438b-8d1b-c7b0ce7dd38d' User entered '10 Nov 2020 20:47'	System	11 Nov 2020 02:47:48
	System	11 Nov 2020 02:47:48

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '10 Nov 2020 15:53'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '11 Nov 2020 11:59'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 2'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-11T17:03:35', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b1c23bd4-be84-4c32-bf77-5afe9aaf334f' User entered 'Does not interfere with activity (2)'	System	11 Nov 2020 23:04:03
	System	11 Nov 2020 23:04:03

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-11T17:03:37', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b1c23bd4-be84-4c32-bf77-5afe9aaf334f' User entered 'Yes (Y)'	System	11 Nov 2020 23:04:03
	System	11 Nov 2020 23:04:03

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-11T17:03:42', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b1c23bd4-be84-4c32-bf77-5afe9aaf334f' User entered '20'	System	11 Nov 2020 23:04:03
	System	11 Nov 2020 23:04:03

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-11T17:03:44', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b1c23bd4-be84-4c32-bf77-5afe9aaf334f' User entered 'Yes (Y)'	System	11 Nov 2020 23:04:03
	System	11 Nov 2020 23:04:03

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-11T17:03:47', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b1c23bd4-be84-4c32-bf77-5afe9aaf334f' User entered '20'	System	11 Nov 2020 23:04:03
	System	11 Nov 2020 23:04:03

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-11T17:03:56', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b1c23bd4-be84-4c32-bf77-5afe9aaf334f' User entered 'None (1)'	System	11 Nov 2020 23:04:03
	System	11 Nov 2020 23:04:03

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-11T17:04:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b1c23bd4-be84-4c32-bf77-5afe9aaf334f' User entered '11 Nov 2020 17:04'	System	11 Nov 2020 23:04:03
	System	11 Nov 2020 23:04:03

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '11 Nov 2020 12:00'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '12 Nov 2020 11:59'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 3'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-12T16:51:42', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '9585faec-f43a-4aed-b2ca-559af158aeae' User entered 'Does not interfere with activity (2)'	System	12 Nov 2020 22:52:34
	System	12 Nov 2020 22:52:34

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-12T16:51:45', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '9585faec-f43a-4aed-b2ca-559af158aeae' User entered 'Yes (Y)'	System	12 Nov 2020 22:52:34
	System	12 Nov 2020 22:52:34

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-12T16:52:19', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '9585faec-f43a-4aed-b2ca-559af158aeae' User entered '70'	System	12 Nov 2020 22:52:34
	System	12 Nov 2020 22:52:34

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-12T16:52:22', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '9585faec-f43a-4aed-b2ca-559af158aeae' User entered 'Yes (Y)'	System	12 Nov 2020 22:52:34
	System	12 Nov 2020 22:52:34

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-12T16:52:26', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '9585faec-f43a-4aed-b2ca-559af158aeae' User entered '70'	System	12 Nov 2020 22:52:34
	System	12 Nov 2020 22:52:34

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-12T16:52:28', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '9585faec-f43a-4aed-b2ca-559af158aeae' User entered 'None (1)'	System	12 Nov 2020 22:52:34
	System	12 Nov 2020 22:52:34

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-12T16:52:32', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '9585faec-f43a-4aed-b2ca-559af158aeae' User entered '12 Nov 2020 16:52'	System	12 Nov 2020 22:52:34
	System	12 Nov 2020 22:52:34

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '12 Nov 2020 12:00'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '13 Nov 2020 11:59'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 4'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-13T19:26:04', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'c3e111d8-2c88-4070-87c1-e54dadfe8996'	System	14 Nov 2020 01:27:16
User entered 'Does not interfere with activity (2)'	System	14 Nov 2020 01:27:16

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-13T19:26:10', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'c3e111d8-2c88-4070-87c1-e54dadfe8996'	System	14 Nov 2020 01:27:16
User entered 'Yes (Y)'	System	14 Nov 2020 01:27:16

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-13T19:26:58', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'c3e111d8-2c88-4070-87c1-e54dadfe8996' User entered '50'	System	14 Nov 2020 01:27:16
	System	14 Nov 2020 01:27:16

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-13T19:27:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'c3e111d8-2c88-4070-87c1-e54dadfe8996'	System	14 Nov 2020 01:27:16
User entered 'Yes (Y)'	System	14 Nov 2020 01:27:16

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-13T19:27:04', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'c3e111d8-2c88-4070-87c1-e54dadfe8996' User entered '50'	System	14 Nov 2020 01:27:16
	System	14 Nov 2020 01:27:16

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-13T19:27:10', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'c3e111d8-2c88-4070-87c1-e54dadfe8996' User entered 'None (1)'	System	14 Nov 2020 01:27:16
	System	14 Nov 2020 01:27:16

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-13T19:27:13', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'c3e111d8-2c88-4070-87c1-e54dadfe8996' User entered '13 Nov 2020 19:27'	System	14 Nov 2020 01:27:16
	System	14 Nov 2020 01:27:16

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '13 Nov 2020 12:00'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '14 Nov 2020 11:59'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 5'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-14T21:42:48', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '6ae52203-15c2-495c-9a14-4d21cd6fa42c' User entered 'None (1)'	System	15 Nov 2020 03:43:08
	System	15 Nov 2020 03:43:08

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-14T21:42:50', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '6ae52203-15c2-495c-9a14-4d21cd6fa42c' User entered 'Yes (Y)'	System	15 Nov 2020 03:43:08
	System	15 Nov 2020 03:43:08

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-14T21:42:56', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '6ae52203-15c2-495c-9a14-4d21cd6fa42c' User entered '40'	System	15 Nov 2020 03:43:08
	System	15 Nov 2020 03:43:08

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-14T21:42:59', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '6ae52203-15c2-495c-9a14-4d21cd6fa42c' User entered 'No (N)'	System	15 Nov 2020 03:43:08
	System	15 Nov 2020 03:43:08

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-14T21:43:01', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '6ae52203-15c2-495c-9a14-4d21cd6fa42c' User entered 'None (1)'	System	15 Nov 2020 03:43:08
	System	15 Nov 2020 03:43:08

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-14T21:43:04', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '6ae52203-15c2-495c-9a14-4d21cd6fa42c' User entered '14 Nov 2020 21:43'	System	15 Nov 2020 03:43:08
	System	15 Nov 2020 03:43:08

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '14 Nov 2020 12:00'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '15 Nov 2020 11:59'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 6'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-15T21:25:43', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e29cacd0-00f0-4103-969a-369b3d996daa' User entered 'None (1)'	System	16 Nov 2020 03:26:46
	System	16 Nov 2020 03:26:46

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-15T21:25:46', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e29cacd0-00f0-4103-969a-369b3d996daa' User entered 'No (N)'	System	16 Nov 2020 03:26:46
	System	16 Nov 2020 03:26:46

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-15T21:25:48', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e29cacd0-00f0-4103-969a-369b3d996daa' User entered 'Yes (Y)'	System	16 Nov 2020 03:26:46
	System	16 Nov 2020 03:26:46

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-15T21:26:31', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e29cacd0-00f0-4103-969a-369b3d996daa' User entered '15'	System	16 Nov 2020 03:26:46
	System	16 Nov 2020 03:26:46

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-15T21:26:35', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e29cacd0-00f0-4103-969a-369b3d996daa' User entered 'None (1)'	System	16 Nov 2020 03:26:46
	System	16 Nov 2020 03:26:46

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-15T21:26:43', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e29cacd0-00f0-4103-969a-369b3d996daa' User entered '15 Nov 2020 21:26'	System	16 Nov 2020 03:26:46
	System	16 Nov 2020 03:26:46

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '15 Nov 2020 12:00'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '16 Nov 2020 11:59'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 7'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-16T21:09:33', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd0b8d7ea-25ca-4b14-9279-b47f54e48107'	System	17 Nov 2020 03:09:56
User entered 'None (1)'	System	17 Nov 2020 03:09:56

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-16T21:09:39', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd0b8d7ea-25ca-4b14-9279-b47f54e48107' User entered 'No (N)'	System	17 Nov 2020 03:09:56
	System	17 Nov 2020 03:09:56

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-16T21:09:41', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd0b8d7ea-25ca-4b14-9279-b47f54e48107' User entered 'Yes (Y)'	System	17 Nov 2020 03:09:56
	System	17 Nov 2020 03:09:56

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-16T21:09:46', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd0b8d7ea-25ca-4b14-9279-b47f54e48107' User entered '15'	System	17 Nov 2020 03:09:56
	System	17 Nov 2020 03:09:56

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-16T21:09:49', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd0b8d7ea-25ca-4b14-9279-b47f54e48107' User entered 'None (1)'	System	17 Nov 2020 03:09:56
	System	17 Nov 2020 03:09:56

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-16T21:09:54', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd0b8d7ea-25ca-4b14-9279-b47f54e48107' User entered '16 Nov 2020 21:09'	System	17 Nov 2020 03:09:56
	System	17 Nov 2020 03:09:56

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '16 Nov 2020 12:00'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '17 Nov 2020 11:59'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T12:30:36', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '373ebe72-2638-4657-90e1-e00935bf0bb8' User entered 'None (0)'	System	10 Nov 2020 18:30:52
	System	10 Nov 2020 18:30:52

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T12:30:38', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '373ebe72-2638-4657-90e1-e00935bf0bb8' User entered 'None (0)'	System	10 Nov 2020 18:30:52
	System	10 Nov 2020 18:30:52

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T12:30:39', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '373ebe72-2638-4657-90e1-e00935bf0bb8' User entered 'None (0)'	System	10 Nov 2020 18:30:52
	System	10 Nov 2020 18:30:52

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T12:30:41', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '373ebe72-2638-4657-90e1-e00935bf0bb8' User entered 'None (0)'	System	10 Nov 2020 18:30:52
	System	10 Nov 2020 18:30:52

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T12:30:43', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '373ebe72-2638-4657-90e1-e00935bf0bb8' User entered 'None (0)'	System	10 Nov 2020 18:30:52
	System	10 Nov 2020 18:30:52

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T12:30:44', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '373ebe72-2638-4657-90e1-e00935bf0bb8' User entered 'None (0)'	System	10 Nov 2020 18:30:52
	System	10 Nov 2020 18:30:52

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

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)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T12:30:46', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '373ebe72-2638-4657-90e1-e00935bf0bb8' User entered 'No (N)'	System	10 Nov 2020 18:30:52
	System	10 Nov 2020 18:30:52

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T12:30:50', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '373ebe72-2638-4657-90e1-e00935bf0bb8' User entered '10 Nov 2020 12:30'	System	10 Nov 2020 18:30:52
	System	10 Nov 2020 18:30:52

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '10 Nov 2020 12:28'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '10 Nov 2020 14:58'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 1, after vaccination (at home)'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T20:47:49', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '6431e4b7-658e-4e92-b8ab-8b301e9d7156' User entered 'None (0)'	System	11 Nov 2020 02:48:08
	System	11 Nov 2020 02:48:08

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T20:47:51', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '6431e4b7-658e-4e92-b8ab-8b301e9d7156' User entered 'None (0)'	System	11 Nov 2020 02:48:08
	System	11 Nov 2020 02:48:08

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T20:47:53', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '6431e4b7-658e-4e92-b8ab-8b301e9d7156' User entered 'None (0)'	System	11 Nov 2020 02:48:08
	System	11 Nov 2020 02:48:08

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T20:47:56', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '6431e4b7-658e-4e92-b8ab-8b301e9d7156' User entered 'None (0)'	System	11 Nov 2020 02:48:08
	System	11 Nov 2020 02:48:08

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T20:47:57', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '6431e4b7-658e-4e92-b8ab-8b301e9d7156' User entered 'None (0)'	System	11 Nov 2020 02:48:08
	System	11 Nov 2020 02:48:08

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T20:47:59', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '6431e4b7-658e-4e92-b8ab-8b301e9d7156' User entered 'None (0)'	System	11 Nov 2020 02:48:08
	System	11 Nov 2020 02:48:08

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

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)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T20:48:02', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '6431e4b7-658e-4e92-b8ab-8b301e9d7156' User entered 'No (N)'	System	11 Nov 2020 02:48:08
	System	11 Nov 2020 02:48:08

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-10T20:48:06', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '6431e4b7-658e-4e92-b8ab-8b301e9d7156' User entered '10 Nov 2020 20:48'	System	11 Nov 2020 02:48:08
	System	11 Nov 2020 02:48:08

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '10 Nov 2020 15:53'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '11 Nov 2020 11:59'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 2'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-11T17:04:05', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e97d4a19-88a0-4abe-9202-77f28d5cf66b' User entered 'No interference with activity (1)'	System	11 Nov 2020 23:04:36
	System	11 Nov 2020 23:04:36

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-11T17:04:07', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e97d4a19-88a0-4abe-9202-77f28d5cf66b' User entered 'No interference with activity (1)'	System	11 Nov 2020 23:04:36
	System	11 Nov 2020 23:04:36

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-11T17:04:11', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e97d4a19-88a0-4abe-9202-77f28d5cf66b' User entered 'Some interference with activity (2)'	System	11 Nov 2020 23:04:36
	System	11 Nov 2020 23:04:36

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-11T17:04:19', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e97d4a19-88a0-4abe-9202-77f28d5cf66b' User entered 'None (0)'	System	11 Nov 2020 23:04:36
	System	11 Nov 2020 23:04:36

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-11T17:04:21', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e97d4a19-88a0-4abe-9202-77f28d5cf66b' User entered 'None (0)'	System	11 Nov 2020 23:04:36
	System	11 Nov 2020 23:04:36

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-11T17:04:24', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e97d4a19-88a0-4abe-9202-77f28d5cf66b' User entered 'None (0)'	System	11 Nov 2020 23:04:36
	System	11 Nov 2020 23:04:36

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

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)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-11T17:04:28', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e97d4a19-88a0-4abe-9202-77f28d5cf66b' User entered 'No (N)'	System	11 Nov 2020 23:04:36
	System	11 Nov 2020 23:04:36

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-11T17:04:32', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'e97d4a19-88a0-4abe-9202-77f28d5cf66b' User entered '11 Nov 2020 17:04'	System	11 Nov 2020 23:04:36
	System	11 Nov 2020 23:04:36

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '11 Nov 2020 12:00'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '12 Nov 2020 11:59'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 3'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-12T16:52:35', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '293fe72a-12b2-48ff-b6ea-906c942bb335' User entered 'None (0)'	System	12 Nov 2020 22:52:55
	System	12 Nov 2020 22:52:55

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-12T16:52:37', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '293fe72a-12b2-48ff-b6ea-906c942bb335'	System	12 Nov 2020 22:52:55
User entered 'No interference with activity (1)'	System	12 Nov 2020 22:52:55

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-12T16:52:39', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '293fe72a-12b2-48ff-b6ea-906c942bb335' User entered 'None (0)'	System	12 Nov 2020 22:52:55
	System	12 Nov 2020 22:52:55

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-12T16:52:41', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '293fe72a-12b2-48ff-b6ea-906c942bb335' User entered 'None (0)'	System	12 Nov 2020 22:52:55
	System	12 Nov 2020 22:52:55

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-12T16:52:42', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '293fe72a-12b2-48ff-b6ea-906c942bb335' User entered 'None (0)'	System	12 Nov 2020 22:52:55
	System	12 Nov 2020 22:52:55

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-12T16:52:44', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '293fe72a-12b2-48ff-b6ea-906c942bb335' User entered 'None (0)'	System	12 Nov 2020 22:52:55
	System	12 Nov 2020 22:52:55

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

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)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-12T16:52:49', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '293fe72a-12b2-48ff-b6ea-906c942bb335' User entered 'No (N)'	System	12 Nov 2020 22:52:55
	System	12 Nov 2020 22:52:55

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-12T16:52:51', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '293fe72a-12b2-48ff-b6ea-906c942bb335'	System	12 Nov 2020 22:52:55
User entered '12 Nov 2020 16:52'	System	12 Nov 2020 22:52:55

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '12 Nov 2020 12:00'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '13 Nov 2020 11:59'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 4'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-13T19:27:17', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '2dba4830-fb84-4452-8119-e0f1a8d213ee' User entered 'None (0)'	System	14 Nov 2020 01:27:43
	System	14 Nov 2020 01:27:43

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-13T19:27:26', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '2dba4830-fb84-4452-8119-e0f1a8d213ee' User entered 'None (0)'	System	14 Nov 2020 01:27:43
	System	14 Nov 2020 01:27:43

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-13T19:27:28', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '2dba4830-fb84-4452-8119-e0f1a8d213ee' User entered 'None (0)'	System	14 Nov 2020 01:27:43
	System	14 Nov 2020 01:27:43

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-13T19:27:31', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '2dba4830-fb84-4452-8119-e0f1a8d213ee' User entered 'None (0)'	System	14 Nov 2020 01:27:43
	System	14 Nov 2020 01:27:43

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-13T19:27:33', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '2dba4830-fb84-4452-8119-e0f1a8d213ee' User entered 'None (0)'	System	14 Nov 2020 01:27:43
	System	14 Nov 2020 01:27:43

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-13T19:27:35', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '2dba4830-fb84-4452-8119-e0f1a8d213ee' User entered 'None (0)'	System	14 Nov 2020 01:27:43
	System	14 Nov 2020 01:27:43

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

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)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-13T19:27:37', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '2dba4830-fb84-4452-8119-e0f1a8d213ee' User entered 'No (N)'	System	14 Nov 2020 01:27:43
	System	14 Nov 2020 01:27:43

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-13T19:27:40', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '2dba4830-fb84-4452-8119-e0f1a8d213ee' User entered '13 Nov 2020 19:27'	System	14 Nov 2020 01:27:43
	System	14 Nov 2020 01:27:43

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '13 Nov 2020 12:00'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '14 Nov 2020 11:59'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 5'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-14T21:43:10', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'f55f0efe-fecc-4185-8f76-e397ff372515' User entered 'None (0)'	System	15 Nov 2020 03:43:34
	System	15 Nov 2020 03:43:34

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-14T21:43:12', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'f55f0efe-fecc-4185-8f76-e397ff372515' User entered 'None (0)'	System	15 Nov 2020 03:43:34
	System	15 Nov 2020 03:43:34

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-14T21:43:13', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'f55f0efe-fecc-4185-8f76-e397ff372515' User entered 'None (0)'	System	15 Nov 2020 03:43:34
	System	15 Nov 2020 03:43:34

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-14T21:43:15', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'f55f0efe-fecc-4185-8f76-e397ff372515' User entered 'None (0)'	System	15 Nov 2020 03:43:34
	System	15 Nov 2020 03:43:34

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-14T21:43:16', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'f55f0efe-fecc-4185-8f76-e397ff372515' User entered 'None (0)'	System	15 Nov 2020 03:43:34
	System	15 Nov 2020 03:43:34

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-14T21:43:17', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'f55f0efe-fecc-4185-8f76-e397ff372515' User entered 'None (0)'	System	15 Nov 2020 03:43:34
	System	15 Nov 2020 03:43:34

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

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)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-14T21:43:20', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'f55f0efe-fecc-4185-8f76-e397ff372515' User entered 'No (N)'	System	15 Nov 2020 03:43:34
	System	15 Nov 2020 03:43:34

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-14T21:43:32', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'f55f0efe-fecc-4185-8f76-e397ff372515' User entered '14 Nov 2020 21:43'	System	15 Nov 2020 03:43:34
	System	15 Nov 2020 03:43:34

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '14 Nov 2020 12:00'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '15 Nov 2020 11:59'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 6'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-15T21:26:49', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '611094e3-bb3a-46b5-9364-c10b60d16b92' User entered 'None (0)'	System	16 Nov 2020 03:27:06
	System	16 Nov 2020 03:27:06

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-15T21:26:51', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '611094e3-bb3a-46b5-9364-c10b60d16b92' User entered 'None (0)'	System	16 Nov 2020 03:27:06
	System	16 Nov 2020 03:27:06

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-15T21:26:53', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '611094e3-bb3a-46b5-9364-c10b60d16b92' User entered 'None (0)'	System	16 Nov 2020 03:27:06
	System	16 Nov 2020 03:27:06

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-15T21:26:54', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '611094e3-bb3a-46b5-9364-c10b60d16b92' User entered 'None (0)'	System	16 Nov 2020 03:27:06
	System	16 Nov 2020 03:27:06

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-15T21:26:56', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '611094e3-bb3a-46b5-9364-c10b60d16b92' User entered 'None (0)'	System	16 Nov 2020 03:27:06
	System	16 Nov 2020 03:27:06

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-15T21:26:58', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '611094e3-bb3a-46b5-9364-c10b60d16b92' User entered 'None (0)'	System	16 Nov 2020 03:27:06
	System	16 Nov 2020 03:27:06

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

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)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-15T21:27:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '611094e3-bb3a-46b5-9364-c10b60d16b92'	System	16 Nov 2020 03:27:06
User entered 'No (N)'	System	16 Nov 2020 03:27:06

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-15T21:27:04', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '611094e3-bb3a-46b5-9364-c10b60d16b92' User entered '15 Nov 2020 21:27'	System	16 Nov 2020 03:27:06
	System	16 Nov 2020 03:27:06

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '15 Nov 2020 12:00'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '16 Nov 2020 11:59'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	10 Nov 2020 18:10:23
User entered 'Day 7'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-16T21:09:58', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '79423242-380d-4dad-9bf4-14f24eeae4e5' User entered 'None (0)'	System	17 Nov 2020 03:10:25
	System	17 Nov 2020 03:10:25

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-16T21:10:07', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '79423242-380d-4dad-9bf4-14f24eeae4e5' User entered 'None (0)'	System	17 Nov 2020 03:10:25
	System	17 Nov 2020 03:10:25

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-16T21:10:09', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '79423242-380d-4dad-9bf4-14f24eeae4e5' User entered 'None (0)'	System	17 Nov 2020 03:10:25
	System	17 Nov 2020 03:10:25

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-16T21:10:10', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '79423242-380d-4dad-9bf4-14f24eeae4e5' User entered 'None (0)'	System	17 Nov 2020 03:10:25
	System	17 Nov 2020 03:10:25

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-16T21:10:11', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '79423242-380d-4dad-9bf4-14f24eeae4e5' User entered 'None (0)'	System	17 Nov 2020 03:10:25
	System	17 Nov 2020 03:10:25

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-16T21:10:13', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '79423242-380d-4dad-9bf4-14f24eeae4e5' User entered 'None (0)'	System	17 Nov 2020 03:10:25
	System	17 Nov 2020 03:10:25

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

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)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-16T21:10:16', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '79423242-380d-4dad-9bf4-14f24eeae4e5' User entered 'No (N)'	System	17 Nov 2020 03:10:25
	System	17 Nov 2020 03:10:25

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-16T21:10:23', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '79423242-380d-4dad-9bf4-14f24eeae4e5' User entered '16 Nov 2020 21:10'	System	17 Nov 2020 03:10:25
	System	17 Nov 2020 03:10:25

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '16 Nov 2020 12:00'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '17 Nov 2020 11:59'	System	10 Nov 2020 18:10:23

US3322429

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	16 Nov 2020 03:26:46
User entered 'Day 8'	System	16 Nov 2020 03:26:46

US3322429

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38

US3322429

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 17:07:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38

US3322429

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 17:07:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38

US3322429

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '17 Nov 2020 12:00'	System	16 Nov 2020 03:26:46

US3322429

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '18 Nov 2020 11:59'	System	16 Nov 2020 03:26:46

US3322429

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	17 Nov 2020 03:09:56
User entered 'Day 9'	System	17 Nov 2020 03:09:56

US3322429

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-19T07:58:32', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b782ed40-9eb2-4a2a-8604-372178921918' User entered 'Yes (Y)'	System	19 Nov 2020 13:58:45
	System	19 Nov 2020 13:58:45

US3322429

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 09 Jun 2021 17:07:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-19T07:58:37', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b782ed40-9eb2-4a2a-8604-372178921918' User entered '10'	System	19 Nov 2020 13:58:45
	System	19 Nov 2020 13:58:45

US3322429

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 09 Jun 2021 17:07:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-19T07:58:40', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b782ed40-9eb2-4a2a-8604-372178921918' User entered '19 Nov 2020 07:58'	System	19 Nov 2020 13:58:45
	System	19 Nov 2020 13:58:45

US3322429

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '18 Nov 2020 12:00'	System	17 Nov 2020 03:09:56

US3322429

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '19 Nov 2020 11:59'	System	17 Nov 2020 03:09:56

US3322429

Folder: Diary Dose 2 (1)

Form: Swelling_Day(10)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	19 Nov 2020 13:58:45
User entered 'Day 10'	System	19 Nov 2020 13:58:45

US3322429

Folder: Diary Dose 2 (1)

Form: Swelling_Day(10)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-19T23:10:17', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '99b79a26-af50-4dca-bc14-6deacb15c8a9' User entered 'No (N)'	System	20 Nov 2020 05:10:49
	System	20 Nov 2020 05:10:49

US3322429

Folder: Diary Dose 2 (1)

Form: Swelling_Day(10)

Generated On: 09 Jun 2021 17:07:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-19T23:10:20', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '99b79a26-af50-4dca-bc14-6deacb15c8a9' User entered '19 Nov 2020 23:10'	System	20 Nov 2020 05:10:49
	System	20 Nov 2020 05:10:49

US3322429

Folder: Diary Dose 2 (1)

Form: Swelling_Day(10)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '19 Nov 2020 12:00'	System	19 Nov 2020 13:58:45

US3322429

Folder: Diary Dose 2 (1)

Form: Swelling_Day(10)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '20 Nov 2020 11:59'	System	19 Nov 2020 13:58:45

US3322429

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	16 Nov 2020 03:26:46
User entered 'Day 8'	System	16 Nov 2020 03:26:46

US3322429

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:07:21

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)	01 May 2021 19:41:38

US3322429

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:07:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38

US3322429

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '17 Nov 2020 12:00'	System	16 Nov 2020 03:26:46

US3322429

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '18 Nov 2020 11:59'	System	16 Nov 2020 03:26:46

US3322429

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	17 Nov 2020 03:09:56
User entered 'Day 9'	System	17 Nov 2020 03:09:56

US3322429

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:07:21

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)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-19T07:58:48', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'f5e86dfe-278c-4a39-a66c-cb4893ef2700' User entered 'No (N)'	System	19 Nov 2020 13:58:53
	System	19 Nov 2020 13:58:53

US3322429

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:07:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-19T07:58:51', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'f5e86dfe-278c-4a39-a66c-cb4893ef2700' User entered '19 Nov 2020 07:58'	System	19 Nov 2020 13:58:53
	System	19 Nov 2020 13:58:53

US3322429

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '18 Nov 2020 12:00'	System	17 Nov 2020 03:09:56

US3322429

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '19 Nov 2020 11:59'	System	17 Nov 2020 03:09:56

US3322429

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
Data entry locked.	System	19 Nov 2020 13:58:45
User entered 'Day 10'	System	19 Nov 2020 13:58:45

US3322429

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:07:21

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)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-19T23:10:24', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '94aea10d-2676-4c45-b740-653dc90a85b6' User entered 'No (N)'	System	20 Nov 2020 05:10:55
	System	20 Nov 2020 05:10:55

US3322429

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:07:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-11-19T23:10:26', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '94aea10d-2676-4c45-b740-653dc90a85b6' User entered '19 Nov 2020 23:10'	System	20 Nov 2020 05:10:55
	System	20 Nov 2020 05:10:55

US3322429

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:07:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '19 Nov 2020 12:00'	System	19 Nov 2020 13:58:45

US3322429

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:07:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:41:38
User entered '20 Nov 2020 11:59'	System	19 Nov 2020 13:58:45

US3322429

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	18 Nov 2020 17:05:58

US3322429

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '18 Nov 2020'	Elisa Moralez (b) (4)	18 Nov 2020 17:05:58

US3322429

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	18 Nov 2020 17:05:58

US3322429

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	18 Nov 2020 17:05:58

US3322429

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	18 Nov 2020 17:05:49

US3322429

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'I'	System	18 Nov 2020 17:05:49

US3322429

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	24 Nov 2020 20:26:27

US3322429

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '24 Nov 2020'	Elisa Moralez (b) (4)	24 Nov 2020 20:26:27

US3322429

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	24 Nov 2020 20:26:27

US3322429

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	24 Nov 2020 20:26:27

US3322429

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	24 Nov 2020 20:26:19

US3322429

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'I'	System	24 Nov 2020 20:26:19

US3322429

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	01 Dec 2020 17:36:27

US3322429

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '01 Dec 2020'	Elisa Moralez (b) (4)	01 Dec 2020 17:36:27

US3322429

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	01 Dec 2020 17:36:27

US3322429

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	01 Dec 2020 17:36:27

US3322429

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	01 Dec 2020 17:36:33

US3322429

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'I'	System	01 Dec 2020 17:36:33

US3322429

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:24:20

US3322429

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '08 Dec 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:24:34
User entered '8 Dec 2020'		08 Dec 2020 16:24:20

US3322429

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:24:20

US3322429

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'VISIT3'	System	08 Dec 2020 16:24:20

US3322429

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:25:31

US3322429

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '08 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:25:31

US3322429

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '09:03'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:25:31

US3322429

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered '08 Dec 2020 09:03'	System	08 Dec 2020 16:25:31

US3322429

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:25:31

US3322429

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:25:31

US3322429

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:25:31

US3322429

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '70'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:25:31

US3322429

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'bpm'	System	08 Dec 2020 16:25:31

US3322429

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '16'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:25:31

US3322429

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'breaths/min'	System	08 Dec 2020 16:25:31

US3322429

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '100'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:25:31

US3322429

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'mmHg'	System	08 Dec 2020 16:25:31

US3322429

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '63'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:25:31

US3322429

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'mmHg'	System	08 Dec 2020 16:25:31

US3322429

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26

US3322429

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26

US3322429

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:25:47

US3322429

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '08 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:25:47

US3322429

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:26:01

US3322429

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '08 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:26:01

US3322429

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '09:33'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:26:01

US3322429

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered '08 Dec 2020 09:33'	System	08 Dec 2020 16:26:01

US3322429

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:26:05

US3322429

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'I'	System	08 Dec 2020 16:26:05

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-12-11T10:49:02', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '29d960d7-facc-4dca-8185-42960fdebab7' User entered 'No (N)'	System	11 Dec 2020 16:49:12
	System	11 Dec 2020 16:49:12

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Have you been exposed to someone with 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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-12-11T10:49:07', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '29d960d7-facc-4dca-8185-42960fdebab7' User entered 'No (N)'	System	11 Dec 2020 16:49:12
	System	11 Dec 2020 16:49:12

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-12-11T10:49:10', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '29d960d7-facc-4dca-8185-42960fdebab7' User entered '11 Dec 2020 10:49:10'	System	11 Dec 2020 16:49:12
	System	11 Dec 2020 16:49:12

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-12-18T12:09:45', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '1682cdde-c2c7-484c-939f-026db84a5486' User entered 'No (N)'	System	18 Dec 2020 18:09:52
	System	18 Dec 2020 18:09:52

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Have you been exposed to someone with 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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-12-18T12:09:47', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '1682cdde-c2c7-484c-939f-026db84a5486' User entered 'No (N)'	System	18 Dec 2020 18:09:52
	System	18 Dec 2020 18:09:52

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-12-18T12:09:50', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '1682cdde-c2c7-484c-939f-026db84a5486' User entered '18 Dec 2020 12:09:50'	System	18 Dec 2020 18:09:52
	System	18 Dec 2020 18:09:52

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-12-26T12:22:29', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '0ceb9af9-110b-4bcb-84a8-98e7f8b6d169' User entered 'No (N)'	System	26 Dec 2020 18:22:39
	System	26 Dec 2020 18:22:39

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Have you been exposed to someone with 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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-12-26T12:22:31', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '0ceb9af9-110b-4bcb-84a8-98e7f8b6d169' User entered 'No (N)'	System	26 Dec 2020 18:22:39
	System	26 Dec 2020 18:22:39

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2020-12-26T12:22:34', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '0ceb9af9-110b-4bcb-84a8-98e7f8b6d169' User entered '26 Dec 2020 12:22:34'	System	26 Dec 2020 18:22:39
	System	26 Dec 2020 18:22:39

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-01T10:17:07', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'ccd60f45-9f13-4866-b253-6f475e52aef7' User entered 'Yes (Y)'	System	01 Jan 2021 16:17:44
	System	01 Jan 2021 16:17:44

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Have you been exposed to someone with 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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-01T10:17:11', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'ccd60f45-9f13-4866-b253-6f475e52aef7'	System	01 Jan 2021 16:17:44
User entered 'No (N)'	System	01 Jan 2021 16:17:44

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-01T10:17:14', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'ccd60f45-9f13-4866-b253-6f475e52aef7' User entered 'No (N)'	System	01 Jan 2021 16:17:44
	System	01 Jan 2021 16:17:44

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-01T10:17:25', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'ccd60f45-9f13-4866-b253-6f475e52aef7' User entered 'Yes (Y)'	System	01 Jan 2021 16:17:44
	System	01 Jan 2021 16:17:44

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-01T10:17:32', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'ccd60f45-9f13-4866-b253-6f475e52aef7'	System	01 Jan 2021 16:17:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Jan 2021 16:17:44

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-01T10:17:35', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'ccd60f45-9f13-4866-b253-6f475e52aef7' User entered '01 Jan 2021 10:17:35'	System	01 Jan 2021 16:17:44
	System	01 Jan 2021 16:17:44

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-08T04:19:46', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b3be9f15-6d58-4882-a2e6-e303bf4b884b' User entered 'Yes (Y)'	System	08 Jan 2021 10:20:04
	System	08 Jan 2021 10:20:04

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Have you been exposed to someone with 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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-08T04:19:41', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b3be9f15-6d58-4882-a2e6-e303bf4b884b' User entered 'No (N)'	System	08 Jan 2021 10:20:04

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-08T04:19:38', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b3be9f15-6d58-4882-a2e6-e303bf4b884b' User entered 'No (N)'	System	08 Jan 2021 10:20:04
	System	08 Jan 2021 10:20:04

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-08T04:19:36', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b3be9f15-6d58-4882-a2e6-e303bf4b884b' User entered 'Yes (Y)'	System	08 Jan 2021 10:20:04
	System	08 Jan 2021 10:20:04

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-08T04:19:50', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b3be9f15-6d58-4882-a2e6-e303bf4b884b'	System	08 Jan 2021 10:20:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Jan 2021 10:20:04

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-08T04:19:55', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b3be9f15-6d58-4882-a2e6-e303bf4b884b' User entered '08 Jan 2021 04:19:55'	System	08 Jan 2021 10:20:04
	System	08 Jan 2021 10:20:04

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:01', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d' User entered 'Yes (Y)'	System	15 Jan 2021 17:13:37
	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Have you been exposed to someone with 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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:04', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d' User entered 'Yes (Y)'	System	15 Jan 2021 17:13:37
	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:08', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d'	System	15 Jan 2021 17:13:37
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:14', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d' User entered 'Yes (Y)'	System	15 Jan 2021 17:13:37
	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:18', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d' User entered '0'	System	15 Jan 2021 17:13:37
	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:18', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d' User entered '0'	System	15 Jan 2021 17:13:37
	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:18', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d' User entered '1'	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:18', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d' User entered '0'	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:18', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d' User entered '0'	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:18', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d' User entered '0'	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:18', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d' User entered '0'	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:18', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d' User entered '0'	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:18', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d' User entered '0'	System	15 Jan 2021 17:13:37
	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:18', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d' User entered '0'	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:18', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d' User entered '0'	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:18', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d' User entered '0'	System	15 Jan 2021 17:13:37
	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:18', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d' User entered '0'	System	15 Jan 2021 17:13:37
	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:18', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d' User entered '0'	System	15 Jan 2021 17:13:37
	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:18', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d' User entered '0'	System	15 Jan 2021 17:13:37
	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:18', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d' User entered '0'	System	15 Jan 2021 17:13:37
	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:18', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d' User entered '0'	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:20', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d'	System	15 Jan 2021 17:13:37
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:23', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d' User entered 'Yes (Y)'	System	15 Jan 2021 17:13:37
	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:25', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d'	System	15 Jan 2021 17:13:37
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-15T11:13:28', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '8fdc358e-24c6-4317-ae08-433a27eae18d' User entered '15 Jan 2021 11:13:28'	System	15 Jan 2021 17:13:37
	System	15 Jan 2021 17:13:37

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-22T17:42:18', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'c2994bcb-159e-48d2-b909-cdcca64eae4d' User entered 'No (N)'	System	22 Jan 2021 23:42:34
	System	22 Jan 2021 23:42:34

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Have you been exposed to someone with 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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-22T17:42:25', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'c2994bcb-159e-48d2-b909-cdcca64eae4d' User entered 'No (N)'	System	22 Jan 2021 23:42:34

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-01-22T17:42:28', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'c2994bcb-159e-48d2-b909-cdcca64eae4d' User entered '22 Jan 2021 17:42:28'	System	22 Jan 2021 23:42:34
	System	22 Jan 2021 23:42:34

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-02-01T08:44:18', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd6795a70-4409-4289-bac8-e5a496331128' User entered 'No (N)'	System	01 Feb 2021 14:44:28

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Have you been exposed to someone with 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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-02-01T08:44:20', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd6795a70-4409-4289-bac8-e5a496331128'	System	01 Feb 2021 14:44:28
User entered 'No (N)'	System	01 Feb 2021 14:44:28

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-02-01T08:44:23', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd6795a70-4409-4289-bac8-e5a496331128' User entered '01 Feb 2021 08:44:23'	System	01 Feb 2021 14:44:28
	System	01 Feb 2021 14:44:28

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-02-05T09:21:05', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'cef6b15d-e749-44ca-bbd6-8cfb29b7face' User entered 'No (N)'	System	05 Feb 2021 15:21:31
	System	05 Feb 2021 15:21:31

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Have you been exposed to someone with 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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-02-05T09:21:20', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'cef6b15d-e749-44ca-bbd6-8cfb29b7face' User entered 'No (N)'	System	05 Feb 2021 15:21:31

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-02-05T09:21:27', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'cef6b15d-e749-44ca-bbd6-8cfb29b7face'	System	05 Feb 2021 15:21:31
User entered '05 Feb 2021 09:21:27'	System	05 Feb 2021 15:21:31

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-02-12T09:03:52', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '026dc6bb-6eea-42f1-a62f-80ad08bb017b' User entered 'No (N)'	System	12 Feb 2021 15:04:09
	System	12 Feb 2021 15:04:09

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Have you been exposed to someone with 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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-02-12T09:04:03', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '026dc6bb-6eea-42f1-a62f-80ad08bb017b' User entered 'No (N)'	System	12 Feb 2021 15:04:09

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-02-12T09:04:06', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '026dc6bb-6eea-42f1-a62f-80ad08bb017b' User entered '12 Feb 2021 09:04:06'	System	12 Feb 2021 15:04:09
	System	12 Feb 2021 15:04:09

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-02-19T10:27:51', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '0ee59294-9f4e-49f7-8b74-53a11cdcf2c'	System	19 Feb 2021 16:27:58
User entered 'No (N)'	System	19 Feb 2021 16:27:58

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Have you been exposed to someone with 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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-02-19T10:27:53', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '0ee59294-9f4e-49f7-8b74-53a11cdcf2c'	System	19 Feb 2021 16:27:58
User entered 'No (N)'	System	19 Feb 2021 16:27:58

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-02-19T10:27:56', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '0ee59294-9f4e-49f7-8b74-53a11cdcf2c' User entered '19 Feb 2021 10:27:56'	System	19 Feb 2021 16:27:58
	System	19 Feb 2021 16:27:58

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-02-26T10:09:37-06:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '1ea3d6e2-7f92-43b1-9eb2-02e1ce7de3b9'	System	26 Feb 2021 16:10:03
User entered 'No (N)'	System	26 Feb 2021 16:10:03

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Have you been exposed to someone with 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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-02-26T10:09:40-06:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '1ea3d6e2-7f92-43b1-9eb2-02e1ce7de3b9' User entered 'Yes (Y)'	System	26 Feb 2021 16:10:03
	System	26 Feb 2021 16:10:03

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-02-26T10:09:45-06:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '1ea3d6e2-7f92-43b1-9eb2-02e1ce7de3b9'	System	26 Feb 2021 16:10:03
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Feb 2021 16:10:03

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-02-26T10:09:49-06:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '1ea3d6e2-7f92-43b1-9eb2-02e1ce7de3b9'	System	26 Feb 2021 16:10:03
User entered '26 Feb 2021 16:09:49'	System	26 Feb 2021 16:10:03

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-03-08T14:19:37-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b70155e2-10ea-4b26-8a96-0daf3779a774' User entered 'No (N)'	System	08 Mar 2021 19:19:58
	System	08 Mar 2021 19:19:58

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Have you been exposed to someone with 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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-03-08T14:19:40-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b70155e2-10ea-4b26-8a96-0daf3779a774'	System	08 Mar 2021 19:19:58
User entered 'No (N)'	System	08 Mar 2021 19:19:58

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-03-08T14:19:42-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'b70155e2-10ea-4b26-8a96-0daf3779a774'	System	08 Mar 2021 19:19:58
User entered '08 Mar 2021 14:19:42'	System	08 Mar 2021 19:19:58

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-03-12T10:47:40-06:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '3f5af070-d731-49c4-8e66-59f061d6eede' User entered 'Yes (Y)'	System	12 Mar 2021 16:48:07
	System	12 Mar 2021 16:48:07

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Have you been exposed to someone with 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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-03-12T10:47:42-06:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '3f5af070-d731-49c4-8e66-59f061d6eede'	System	12 Mar 2021 16:48:07
User entered 'No (N)'	System	12 Mar 2021 16:48:07

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-03-12T10:47:46-06:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '3f5af070-d731-49c4-8e66-59f061d6eede'	System	12 Mar 2021 16:48:07
User entered 'No (N)'	System	12 Mar 2021 16:48:07

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-03-12T10:47:50-06:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '3f5af070-d731-49c4-8e66-59f061d6eede'	System	12 Mar 2021 16:48:07
User entered 'Yes (Y)'	System	12 Mar 2021 16:48:07

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-03-12T10:47:55-06:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '3f5af070-d731-49c4-8e66-59f061d6eede'	System	12 Mar 2021 16:48:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Mar 2021 16:48:07

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-03-12T10:47:57-06:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '3f5af070-d731-49c4-8e66-59f061d6eede' User entered '12 Mar 2021 10:47:57'	System	12 Mar 2021 16:48:07
	System	12 Mar 2021 16:48:07

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-03-19T10:36:15-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'a4d55c08-bbcb-4336-927a-e66e0783b401'	System	19 Mar 2021 15:36:26
User entered 'No (N)'	System	19 Mar 2021 15:36:26

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Have you been exposed to someone with 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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-03-19T10:36:18-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'a4d55c08-bbcb-4336-927a-e66e0783b401'	System	19 Mar 2021 15:36:26
User entered 'No (N)'	System	19 Mar 2021 15:36:26

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-03-19T10:36:20-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'a4d55c08-bbcb-4336-927a-e66e0783b401'	System	19 Mar 2021 15:36:26
User entered '19 Mar 2021 10:36:20'	System	19 Mar 2021 15:36:26

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-03-30T08:36:37-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'c5e6528d-1cee-4e96-869c-1f008333a9e3' User entered 'No (N)'	System	30 Mar 2021 13:36:48
	System	30 Mar 2021 13:36:48

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Have you been exposed to someone with 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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-03-30T08:36:40-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'c5e6528d-1cee-4e96-869c-1f008333a9e3'	System	30 Mar 2021 13:36:48
User entered 'No (N)'	System	30 Mar 2021 13:36:48

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-03-30T08:36:43-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'c5e6528d-1cee-4e96-869c-1f008333a9e3' User entered '30 Mar 2021 08:36:43'	System	30 Mar 2021 13:36:48
	System	30 Mar 2021 13:36:48

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-04-02T16:35:06-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '0e5fb1b8-c195-4471-a23c-b0d4601cd31c' User entered 'No (N)'	System	02 Apr 2021 21:35:23
	System	02 Apr 2021 21:35:23

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Have you been exposed to someone with 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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-04-02T16:35:16-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '0e5fb1b8-c195-4471-a23c-b0d4601cd31c' User entered 'No (N)'	System	02 Apr 2021 21:35:23
	System	02 Apr 2021 21:35:23

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-04-02T16:35:19-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '0e5fb1b8-c195-4471-a23c-b0d4601cd31c' User entered '02 Apr 2021 16:35:19'	System	02 Apr 2021 21:35:23
	System	02 Apr 2021 21:35:23

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-04-12T05:34:02-06:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '992ebe7b-1d4d-4335-8ca5-7d9d8c801e4b' User entered 'No (N)'	System	12 Apr 2021 11:34:13
	System	12 Apr 2021 11:34:13

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Have you been exposed to someone with 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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-04-12T05:34:05-06:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '992ebe7b-1d4d-4335-8ca5-7d9d8c801e4b'	System	12 Apr 2021 11:34:13
User entered 'No (N)'	System	12 Apr 2021 11:34:13

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-04-12T05:34:11-06:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '992ebe7b-1d4d-4335-8ca5-7d9d8c801e4b'	System	12 Apr 2021 11:34:13
User entered '12 Apr 2021 05:34:11'	System	12 Apr 2021 11:34:13

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-04-19T09:26:24-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '318bda29-089f-4900-8d98-5a57d03ffcc2'	System	19 Apr 2021 14:26:57
User entered 'No (N)'	System	19 Apr 2021 14:26:57

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Have you been exposed to someone with 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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-04-19T09:26:37-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '318bda29-089f-4900-8d98-5a57d03ffcc2'	System	19 Apr 2021 14:26:57
User entered 'Yes (Y)'	System	19 Apr 2021 14:26:57

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-04-19T09:26:43-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '318bda29-089f-4900-8d98-5a57d03ffcc2'	System	19 Apr 2021 14:26:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Apr 2021 14:26:57

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-04-19T09:26:47-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '318bda29-089f-4900-8d98-5a57d03ffcc2'	System	19 Apr 2021 14:26:57
User entered '19 Apr 2021 09:26:47'	System	19 Apr 2021 14:26:57

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-04-23T10:26:29-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '49d03338-3728-426e-b480-a3cdf11f84c2' User entered 'No (N)'	System	23 Apr 2021 15:26:38
	System	23 Apr 2021 15:26:38

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Have you been exposed to someone with 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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-04-23T10:26:23-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '49d03338-3728-426e-b480-a3cdf11f84c2'	System	23 Apr 2021 15:26:38
User entered 'No (N)'	System	23 Apr 2021 15:26:38

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-04-23T10:26:33-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '49d03338-3728-426e-b480-a3cdf11f84c2'	System	23 Apr 2021 15:26:38
User entered '23 Apr 2021 10:26:33'	System	23 Apr 2021 15:26:38

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-05-03T23:49:04-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd43271dc-7885-4678-9231-791e91b960b1'	System	04 May 2021 04:49:13
User entered 'No (N)'	System	04 May 2021 04:49:13

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

Have you been exposed to someone with 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 (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-05-03T23:49:07-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd43271dc-7885-4678-9231-791e91b960b1'	System	04 May 2021 04:49:13
User entered 'No (N)'	System	04 May 2021 04:49:13

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-05-03T23:49:09-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: 'd43271dc-7885-4678-9231-791e91b960b1'	System	04 May 2021 04:49:13
User entered '03 May 2021 23:49:09'	System	04 May 2021 04:49:13

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '25 Nov 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '29 Nov 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '02 Dec 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '06 Dec 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '09 Dec 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '13 Dec 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '16 Dec 2022 00:01'	System	20 Nov 2020 12:33:46

US3322429

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:33:46
Amendment Manager: User entered '20 Dec 2022 23:59'	System	20 Nov 2020 12:33:46

US3322429

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:07:21

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)	30 Apr 2021 15:58:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-03-08T14:19:27-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '0ec74b3b-61c2-479d-8ca3-f048142f61e0' User entered 'No (N)'	System	08 Mar 2021 19:19:37
	System	08 Mar 2021 19:19:37

US3322429

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:07:21

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1922BE2F-22D3-4D7A-8E30-6C382EA6C22F)', Time: '2021-03-08T14:19:30-05:00', User OID: 'PatientReportedOutcome (US3322429)', ODM File OID: '0ec74b3b-61c2-479d-8ca3-f048142f61e0' User entered '08 Mar 2021 14:19:30'	System	08 Mar 2021 19:19:37
	System	08 Mar 2021 19:19:37

US3322429

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	05 Jan 2021 18:12:56

US3322429

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '04 Jan 2021'	Elisa Moralez (b) (4)	05 Jan 2021 18:12:56

US3322429

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	05 Jan 2021 18:12:56

US3322429

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	05 Jan 2021 18:12:56

US3322429

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	05 Jan 2021 18:13:04

US3322429

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:29:26
User entered 'I'	System	05 Jan 2021 18:13:04

US3322429

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:40:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Feb 2021 20:07:24

US3322429

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:40:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '05 Feb 2021'	Elisa Moralez (b) (4)	21 Feb 2021 20:07:24

US3322429

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:40:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	21 Feb 2021 20:07:24

US3322429

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:40:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	21 Feb 2021 20:07:24

US3322429

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:40:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Feb 2021 20:07:28

US3322429

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:40:41
User entered 'I'	System	21 Feb 2021 20:07:28

US3322429

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:40:41
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	10 Mar 2021 20:10:46

US3322429

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:40:41
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered '08 Mar 2021'	Elisa Moralez (b) (4)	10 Mar 2021 20:10:46

US3322429

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:40:41
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	10 Mar 2021 20:10:46

US3322429

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:40:41
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered empty.	Elisa Moralez (b) (4)	10 Mar 2021 20:10:46

US3322429

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:40:41
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	10 Mar 2021 20:10:50

US3322429

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:40:41
User entered 'I'	System	10 Mar 2021 20:10:50

US3322429

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:40:25
User entered 'Yes (Y)'	(b) (4) Elisa Morales (b) (4)	19 Apr 2021 15:37:02
	(b) (4)	

US3322429

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:40:25
	(b) (4)	
User entered '6 Apr 2021'	Elisa Morales (b) (4)	19 Apr 2021 15:37:02
	(b) (4)	

US3322429

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:40:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Morales (b) (4)	19 Apr 2021 15:37:02
	(b) (4)	

US3322429

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:40:25
User entered empty.	(b) (4) Elisa Morales (b) (4)	19 Apr 2021 15:37:02
	(b) (4)	

US3322429

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:40:25
User entered 'Yes (Y)'	(b) (4) Elisa Morales (b) (4)	19 Apr 2021 15:37:06
	(b) (4)	

US3322429

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 15:37:06

US3322429

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

Form: Visit Date

Generated On: 09 Jun 2021 17:07:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	03 Feb 2021 19:47:02

US3322429

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

Form: Visit Date

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '3 Feb 2021'	Elisa Moralez (b) (4)	03 Feb 2021 19:47:02

US3322429

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

Form: Visit Date

Generated On: 09 Jun 2021 17:07:21

[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 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4)	03 Feb 2021 19:47:02

US3322429

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

Form: Visit Date

Generated On: 09 Jun 2021 17:07:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered 'UNBLND_DECIDE'	System	03 Feb 2021 19:47:02

US3322429

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:21

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '03 Feb 2021'	Elisa Moralez (b) (4)	03 Feb 2021 19:47:39

US3322429

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:21

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:48:27

US3322429

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:21

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	03 Feb 2021 19:47:39

US3322429

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:21

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:48:27

US3322429

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:21

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:40:25
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 21:03:46
User closed query 'Per IRT, subject was unblinded on 18JAN2021. Please review and reconcile.' (Site from DM).		09 Apr 2021 21:03:44
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'per IRT' (Site from System).	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 19:02:08
Query 'Per IRT, subject was unblinded on 18JAN2021. Please review and reconcile.' answered with 'updated, thanks!' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 19:02:03
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	08 Apr 2021 19:01:55
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 19:01:55
User entered '18 Jan 2021' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 19:01:55
User opened query 'Per IRT, subject was unblinded on 18JAN2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:20:49
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:15:06
User entered '03 Feb 2021'	Elisa Moralez (b) (4) (b) (4)	03 Feb 2021 19:47:39

US3322429

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:21

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'mRNA-1273 (mRNA-1273)'	Elisa Moralez (b) (4)	03 Feb 2021 19:47:39

US3322429

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:21

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'mRNA-1273 (mRNA-1273)'	Elisa Moralez (b) (4)	03 Feb 2021 19:47:39

US3322429

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:21

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'mRNA-1273 (mRNA-1273)'	Elisa Moralez (b) (4)	03 Feb 2021 19:47:39

US3322429

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:21

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Elisa Moralez (b) (4)	03 Feb 2021 19:47:39

US3322429

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:21

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered empty.	System	03 Feb 2021 19:47:39

US3322429

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:21

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered empty.	System	03 Feb 2021 19:47:39

US3322429

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	03 Feb 2021 19:47:48

US3322429

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '03 Feb 2021'	Elisa Moralez (b) (4)	03 Feb 2021 19:47:48

US3322429

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '13:28'	Elisa Moralez (b) (4)	03 Feb 2021 19:47:48

US3322429

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered '03 Feb 2021 13:28'	System	03 Feb 2021 19:47:48

US3322429

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:07:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	03 Feb 2021 19:48:00

US3322429

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:07:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '03 Feb 2021'	Elisa Moralez (b) (4)	03 Feb 2021 19:48:00

US3322429

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:07:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '13:23'	Elisa Moralez (b) (4)	03 Feb 2021 19:48:00

US3322429

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:07:21

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:12:20
User entered '03 Feb 2021 13:23'	System	03 Feb 2021 19:48:00

US3322429

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:07:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:32:42
DataPoint Verified.		09 Apr 2021 01:46:22
User closed query 'per protocol , medical AEs need to be noted; please include Medical AE Chaga's disease' (Site from CRA).		09 Apr 2021 01:46:10
Query 'per protocol , medical AEs need to be noted; please include Medical AE Chaga's disease' answered with 'thanks' (Site from CRA).	Elisa Moralez (b) (4)	08 Apr 2021 21:34:00
DataPoint Un-verified.	(b) (4)	
	Heather Davis (b) (4)	08 Apr 2021 18:54:15
	(b) (4)	
User opened query 'per protocol , medical AEs need to be noted; please include Medical AE Chaga's disease' (Site from CRA).	Heather Davis (b) (4)	08 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:50
User signature succeeded.	(b) (4)	
	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	09 Dec 2020 17:02:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Rhinorrhea - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 17:05:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 17:05:55
Data point term sent to Coder	System	09 Dec 2020 17:05:12
User entered 'Rhinorrhea'	Elisa Morales (b) (4)	09 Dec 2020 17:04:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '08 Dec 2020'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User entered empty.	System	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '08 Dec 2020'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User entered empty.	System	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Not Applicable (NOT APPLICABLE)'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'I'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User entered '0'	System	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22
User entered '0'	System	09 Dec 2020 17:04:13

US3322429

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:22

US3322429

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31

US3322429

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User closed query 'Per DM CLR: Please review this solicited event and please note that this was already captured on the subject's Diary record and it does not appear to meet any Solicited Adverse Reaction reporting criteria per Protocol section 8.3.4 (e.g., eDiary Day 8 - No Information). Please review and update to delete/remove AE as applicable. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:09:26
Query 'Per DM CLR: Please review this solicited event and please note that this was already captured on the subject's Diary record and it does not appear to meet any Solicited Adverse Reaction reporting criteria per Protocol section 8.3.4 (e.g., eDiary Day 8 - No Information). Please review and update to delete/remove AE as applicable. Otherwise, clarify. ' answered with 'lasted long enough to be past ediary and PI decided it's an AE' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Feb 2021 20:17:57
User opened query 'Per DM CLR: Please review this solicited event and please note that this was already captured on the subject's Diary record and it does not appear to meet any Solicited Adverse Reaction reporting criteria per Protocol section 8.3.4 (e.g., eDiary Day 8 - No Information). Please review and update to delete/remove AE as applicable. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 05:20:47
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site swelling, LLT: Injection site swelling - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 16:33:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 16:33:54
Data point term sent to Coder	System	09 Dec 2020 17:05:13
User entered 'Injection site swelling of left upper arm'	Elisa Moralez (b) (4) (b) (4)	09 Dec 2020 17:04:59

US3322429

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

US3322429

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:45
User closed query 'Per CDM: SAR is recorded as no, however this event is recorded in the eDiary and is a solicited adverse event per protocol. Please review and update.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:31
Query 'Per CDM: SAR is recorded as no, however this event is recorded in the eDiary and is a solicited adverse event per protocol. Please review and update.' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 14:31:35
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 14:31:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 14:31:06
User opened query 'Per CDM: SAR is recorded as no, however this event is recorded in the eDiary and is a solicited adverse event per protocol. Please review and update.' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 19:02:41
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	09 Dec 2020 17:04:59

US3322429

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

US3322429

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '10 Nov 2020'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

US3322429

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Dec 2020 21:03:04
Query 'Data is required. Please provide.' answered with 'not in source, just states morning' (Site from System).	Elisa Moralez (b) (4)	09 Dec 2020 17:32:43
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Dec 2020 17:04:59
User entered empty.	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User entered empty.	System	09 Dec 2020 17:04:59

US3322429

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '19 Nov 2020'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Dec 2020 21:03:06
Query 'Data is required. Please provide.' answered with 'not available in source' (Site from System).	Elisa Moralez (b) (4)	09 Dec 2020 17:32:49
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Dec 2020 17:04:59
User entered empty.	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User entered empty.	System	09 Dec 2020 17:04:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

US3322429

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

US3322429

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

US3322429

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

US3322429

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

US3322429

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

US3322429

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Related (RELATED)'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'None (NONE)'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'I'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

US3322429

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

US3322429

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	09 Dec 2020 17:04:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User entered '0'	System	09 Dec 2020 17:04:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31
User entered '0'	System	09 Dec 2020 17:04:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:07:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:31

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 16:28:45

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' answered with 'patient did not report this until 15-JAN-2021, at which point there was a progress note stating the following, "Subject contacted the study clinic and stated that her husband tested positive to COVID-19 yesterday 14-Jan-2021 and he is quarantined in a room in their home together. The subject stated that she is not having no signs nor symptoms of COVID-19. The subject reported on 08-Jan-2021 she went to the E.R at 10 pm at night and was released from the E.R by 1 am in the morning of 09-Jan-2021 and was not admitted to the hospital,. The subject went to the E.R due to having shortness of breath and a cough. The subject stated that her cough is ongoing as of 15-Jan-2021 only when she goes outside, but her shortness of breath ended on 09-Jan-2021. This occurrence was unrelated to the exposure to COVID-19. The subject stated she went to the E.R due to her believing her reported symptoms had something to do with her surgery done in December (documented in con procedures). The subject stated that her treating doctor started her on Urosdiol 300 mg PO BID for 6 months, sucralfate 1 gram PO four times a day, and Omeprazole 40 mg for gastrointestinal issues. The subject is aware that someone from the study clinic will contact her due to the symptoms reported. The subject expressed an understanding and had no further concerns nor symptoms to report.'" (Site from DM).	Elisa Morales (b) (4) (b) (4)	15 Mar 2021 19:26:07
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 18:12:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #4 (SHORTNESS OF BREATH), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4)	01 Mar 2021 14:47:28
Query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #4 (SHORTNESS OF BREATH), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' answered with 'no' (Site from DM).	Veronica Fragoso (b) (4) (b) (4) Elisa Moralez (b) (4) (b) (4)	26 Feb 2021 04:15:06 25 Feb 2021 17:05:29
User opened query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #4 (SHORTNESS OF BREATH), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	22 Feb 2021 01:40:51
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Feb 2021 19:30:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Feb 2021 19:30:52
Data point term sent to Coder	System	05 Feb 2021 19:30:05
User entered 'Cough'	Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 19:29:57

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	(b) (4) Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	(b) (4) Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	(b) (4) Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered '08 Jan 2021'	Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered empty.	Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 19:29:57

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered 'Yes (Y)'	Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered empty.	Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered empty.	Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 19:29:57

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered 'No (N)'	Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered '0'	Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered '0'	Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	(b) (4) Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	(b) (4) Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	(b) (4) Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered empty.	Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered empty.	Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered '0'	Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered '0'	Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered '0'	Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Not Related (NOT RELATED)'	(b) (4) Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Not Related (NOT RELATED)'	(b) (4) Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Elisa Moralez (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

None

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered 'I'	Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered '0'	Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered '0'	Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Elisa Moralez (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	(b) (4) Elisa Moralez (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	(b) (4) Elisa Morales (b) (4)	05 Feb 2021 19:29:57
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Feb 2021 19:29:57

US3322429

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:07:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 19:29:57

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).		16 Mar 2021 16:29:15

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' answered with 'PN states "Subject contacted the study clinic and stated that her husband tested positive to COVID-19 yesterday 14-Jan-2021 and he is quarantined in a room in their home together. The subject stated that she is not having no signs nor symptoms of COVID-19. The subject reported on 08-Jan-2021 she went to the E.R at 10 pm at night and was released from the E.R by 1 am in the morning of 09-Jan-2021 and was not admitted to the hospital,. The subject went to the E.R due to having shortness of breath and a cough. The subject stated that her cough is ongoing as of 15-Jan-2021 only when she goes outside, but her shortness of breath ended on 09-Jan-2021. This occurrence was unrelated to the exposure to COVID-19. The subject stated she went to the E.R due to her believing her reported symptoms had something to due with her surgery done in December (documented in con procedures). The subject stated that her treating doctor started her on Urosdiol 300 mg PO BID for 6 months, sucralfate 1 gram PO four times a day, and Omeprazole 40 mg for gastrointestinal issues. The subject is aware that someone from the study clinic will contact her due to the symptoms reported. The subject expressed an understanding and had no further concerns nor symptoms to report.'" (Site from DM).	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 19:26:24
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 18:12:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 19:31:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 19:31:49
Data point term sent to Coder	System	05 Feb 2021 19:31:06
User entered 'Shortness of breath'	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '08 Jan 2021'	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User entered empty.	System	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '09 Jan 2021'	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User entered empty.	System	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Not Related (NOT RELATED)'	(b) (4)	
reason for change: Data Entry Error	Elisa Moralez (b) (4)	24 Feb 2021 21:51:14
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Not Applicable (NOT APPLICABLE)'	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'I'	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

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Folder: Adverse Events

Form: Adverse Events (4)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	05 Feb 2021 19:30:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User entered '0'	System	05 Feb 2021 19:30:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45
User entered 'I'	System	05 Feb 2021 19:30:38

US3322429

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:07:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:06
User entered 'USA-US060-2021-mRNA-1273-P301000009'	System	08 Feb 2021 19:33:06
User entered 'New'	(b) (4), (b) (6)	08 Feb 2021 19:33:06

US3322429

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms malignant and unspecified, HLT: Gastrointestinal neoplasms malignant NEC, PT: Gastrointestinal stromal tumour, LLT: Gastrointestinal stromal tumor - version MedDRA\\23.0.	Coder Import (b) (4)	07 Feb 2021 15:49:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Feb 2021 15:49:39
Data point term sent to Coder	System	05 Feb 2021 19:33:08
User entered 'Gatroidintestinal Stromal Tumor'	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

US3322429

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:36
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '31 Dec 2020'	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 19:32:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '31 Dec 2020'	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 19:32:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

US3322429

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

US3322429

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

US3322429

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User closed query 'PV Query: Please consider re-assess Seriousness criteria-Caused/prolonged hospitalization, as the subject was admitted for a planned surgery and she had a normal hospitalization. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 21:20:20
Query 'PV Query: Please consider re-assess Seriousness criteria-Caused/prolonged hospitalization, as the subject was admitted for a planned surgery and she had a normal hospitalization. ' answered with 'this is what PI decided' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	11 Feb 2021 19:36:57
User opened query 'PV Query: Please consider re-assess Seriousness criteria-Caused/prolonged hospitalization, as the subject was admitted for a planned surgery and she had a normal hospitalization. ' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 18:32:58
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		05 Feb 2021 19:32:31
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		05 Feb 2021 19:32:31
User entered '1' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 19:32:31
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	05 Feb 2021 19:32:17
User entered '0'	Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 19:32:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '31 Dec 2020'	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

US3322429

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:41:26
' (Site from Safety). Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.	Elisa Moralez (b) (4) (b) (4)	21 Feb 2021 17:00:01
' answered with 'sent' (Site from Safety). User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.	(b) (4), (b) (6)	11 Feb 2021 18:37:55
' (Site from Safety). User entered '01 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 19:32:17

US3322429

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

US3322429

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

US3322429

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

US3322429

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'I'	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User closed query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:41:30
Query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly. ' answered with 'ok' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	21 Feb 2021 17:00:28
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	21 Feb 2021 17:00:20
User opened query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly. ' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 18:34:20
User entered 'Not Applicable (NOT APPLICABLE)'	Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 19:32:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Not Applicable (NOT APPLICABLE)'	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

US3322429

Folder: Adverse Events

Form: Adverse Events (5)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		26 Feb 2021 15:11:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'everything that is in source is in EDC' (Site from Safety).	Elisa Moralez (b) (4)	25 Feb 2021 19:54:24
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 18:14:07
User entered '0'	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

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Folder: Adverse Events

Form: Adverse Events (5)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User closed query 'PV Query: Dates still have not been provided. Please provide dates of endoscopy and CT of abdomen and lungs. If unknown, please indicate so.' (Site from Safety).		26 Feb 2021 15:11:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Query 'PV Query: Dates still have not been provided. Please provide dates of endoscopy and CT of abdomen and lungs. If unknown, please indicate so.' answered with 'look in concomitant procedures, they've been reported' (Site from Safety).	Elisa Moralez (b) (4)	25 Feb 2021 19:53:59
User opened query 'PV Query: Dates still have not been provided. Please provide dates of endoscopy and CT of abdomen and lungs. If unknown, please indicate so.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 18:13:08
User closed query 'PV Query: Please provide dates of endoscopy and CT of abdomen and lungs.		19 Feb 2021 15:08:01
' (Site from Safety).		
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).		19 Feb 2021 15:07:58
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' answered with 'will update in conproc' (Site from Safety).	Elisa Moralez (b) (4)	18 Feb 2021 21:32:03
Query 'PV Query: Please provide dates of endoscopy and CT of abdomen and lungs.	Elisa Moralez (b) (4)	18 Feb 2021 21:31:48
' answered with 'will update in conproc' (Site from Safety).		
User opened query 'PV Query: Please provide dates of endoscopy and CT of abdomen and lungs.	(b) (4), (b) (6)	11 Feb 2021 18:40:04
' (Site from Safety).		

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Folder: Adverse Events

Form: Adverse Events (5)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety). User entered 'I'	(b) (4), (b) (6) (b) (4)	11 Feb 2021 18:32:11
	Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 19:32:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:20:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

US3322429

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please leave query unanswered until records are sent or, if unable to obtain, please state so. Discharge summary has not been received. Please resend discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). ' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 13:10:20
Query 'PV Query: Please leave query unanswered until records are sent or, if unable to obtain, please state so. Discharge summary has not been received. Please resend discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). ' answered with 'records have been sent, thank you!' (Site from Safety).	Elisa Moralez (b) (4)	27 Apr 2021 01:16:58
User opened query 'PV Query: Please leave query unanswered until records are sent or, if unable to obtain, please state so. Discharge summary has not been received. Please resend discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). ' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 17:26:19
User closed query 'PV Query: Discharge summary has not been received. Please resend discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 14:09:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Discharge summary has not been received. Please resend discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Site has not yet received these documents, response came only yesterday that the request was received. It has not yet been fully processed, but site is attempting to retrieve the information. ' (Site from Safety). User opened query 'PV Query: Discharge summary has not been received. Please resend discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety). DataPoint Verified.	Elisa Morales (b) (4)	21 Apr 2021 14:11:33
User closed query 'Per DM CLR: Narrative = HAD CT OF ABDOMEN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM). User closed query 'PV Query: Discharge summary has not been received. Please resend discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety). User closed query 'PV Query: COVID-19 testing details during hospitalization still have not been provided. Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 20:45:53
		04 Mar 2021 21:20:46
		26 Feb 2021 15:13:03
		26 Feb 2021 14:47:20
		26 Feb 2021 14:47:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Query 'PV Query: Discharge summary has not been received. Please resend discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'still waiting on medical records' (Site from Safety).	Elisa Moralez (b) (4)	25 Feb 2021 20:34:21
Query 'PV Query: COVID-19 testing details during hospitalization still have not been provided. Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'none' (Site from Safety).	Elisa Moralez (b) (4)	25 Feb 2021 19:54:36
User opened query 'PV Query: Discharge summary has not been received. Please resend discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 18:12:42
User opened query 'PV Query: COVID-19 testing details during hospitalization still have not been provided. Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 18:12:32
Query 'Per DM CLR: Narrative = HAD CT OF ABDOMEN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'ct scan of lungs is recorded as entry 7' (Site from DM).	Elisa Moralez (b) (4)	25 Feb 2021 17:06:31
User opened query 'Per DM CLR: Narrative = HAD CT OF ABDOMEN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 01:41:10

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'During safety call today, patient reports that a Gastrointestinal Stromal Tumor was found incidentally on 31DEC2020 during her elective Gastric Bypass surgery. Patient had a normal hospitalization and recovered well and was discharged in stable condition on 01JAN2021. Patient had outpatient follow up at MDAnderson regarding her Gastrointestinal Stromal Tumor with an Oncologist. Due to the size of tumor, patient was told that reoccurrence is 0%. Had CT of Abdomen and Lungs which is reported as negative per patient. Her endoscopy prior to Gastric Bypass was only significant for a benign polyp. Patient will have scheduled follow up every 6 months for several years. Medical record release has already been obtained. Will await review of pending records.'	Elisa Moralez (b) (4)	05 Feb 2021 19:32:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 19:32:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 19:32:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:07:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Feb 2021 19:32:17

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Skin laceration, LLT: Laceration of leg - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 00:35:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 00:35:46
Data point term sent to Coder	System	09 Mar 2021 18:00:31
User entered 'Laceration of left lower leg'	Elisa Moralez (b) (4)	09 Mar 2021 17:59:41

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
	(b) (4)	
User entered 'Yes (Y)'	Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered 'No (N)'	(b) (4) Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered 'No (N)'	(b) (4) Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
	(b) (4)	
User entered '19 Feb 2021'	Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered empty.	(b) (4) Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 17:59:41

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
	(b) (4)	
User entered 'Yes (Y)'	Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered empty.	(b) (4) Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered empty.	(b) (4) Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 17:59:41

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
	(b) (4)	
User entered 'No (N)'	Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

Death

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
	(b) (4)	
User entered '0'	Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
	(b) (4)	
User entered '0'	Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered '0'	(b) (4) Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
	(b) (4)	
User entered empty.	Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered empty.	(b) (4) Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
	(b) (4)	
User entered empty.	Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
	(b) (4)	
User entered empty.	Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
	(b) (4)	
User entered '0'	Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
	(b) (4)	
User entered '0'	Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
	(b) (4)	
User entered '0'	Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered 'Not Related (NOT RELATED)'	(b) (4) Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered 'Not Related (NOT RELATED)'	(b) (4) Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered 'None (NONE)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

None

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
	(b) (4)	
User entered '0'	Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
	(b) (4)	
User entered '0'	Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
	(b) (4)	
User entered 'I'	Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Elisa Moralez (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered empty.	(b) (4) Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered empty.	(b) (4) Elisa Morales (b) (4)	09 Mar 2021 17:59:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	09 Mar 2021 17:59:41

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:07:21

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	09 Mar 2021 17:59:41

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User coded data point as SOC: Infections and infestations, HLGT: Protozoal infectious disorders, HLT: Trypanosomal infections, PT: American trypanosomiasis, LLT: Chagas' disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 22:12:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 22:12:07
Data point term sent to Coder	System	08 Apr 2021 21:34:24
User entered 'Chaga's disease'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

US3322429

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

US3322429

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered '12 Mar 2021'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

US3322429

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 21:33:54

US3322429

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 21:33:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

US3322429

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

US3322429

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

Death

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered '0'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

US3322429

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered '0'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

US3322429

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered '0'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (v) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

US3322429

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

US3322429

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered '0'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered '0'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered '0'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered 'Not Applicable (NOT APPLICABLE)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

None

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:45
Signature has been broken.	(b) (4)	
	Elisa Moralez (b) (4)	23 Apr 2021 16:08:27
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Elisa Moralez (b) (4)	23 Apr 2021 16:08:27
	(b) (4)	
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered '1'	Elisa Moralez (b) (4)	08 Apr 2021 21:33:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	28 Apr 2021 16:20:45
Signature has been broken.	(b) (4) Elisa Moralez (b) (4)	23 Apr 2021 16:08:27
User entered '1' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	23 Apr 2021 16:08:27
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered '0'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered '0'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered empty.	Elisa Moralez (b) (4)	08 Apr 2021 21:33:54
	(b) (4)	

US3322429

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 01:46:53
DataPoint Verified.		09 Apr 2021 01:46:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:33:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	08 Apr 2021 21:33:54

US3322429

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:07:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 21:33:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:32:42
User closed query 'Please add all conmeds taken for Medically attended AEs. Please also confirm the indication corresponds to the AE or SAE noted in the AE page.' (Site from CRA).		09 Apr 2021 13:57:12
Query 'Please add all conmeds taken for Medically attended AEs. Please also confirm the indication corresponds to the AE or SAE noted in the AE page.' answered with 'thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:34:23
User opened query 'Please add all conmeds taken for Medically attended AEs. Please also confirm the indication corresponds to the AE or SAE noted in the AE page.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 16:56:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 16:27:23
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:32:53

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: LISDEXAMFETAMINE MESILATE, PRODUCTSYNONYM: VYVANSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 17:35:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 17:35:34
Data point term sent to Coder	System	14 Oct 2020 17:34:53
User entered 'Vyvanse'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:05

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:05

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Attention deficit disorder'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:05

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '40'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:05

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'mg (mg)'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:05

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:05

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'once daily (QD)'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:05

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:05

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Oral (ORAL)'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:05

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:05

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'UN UNK 2019'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:05

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:05

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:05

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:05

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:05

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 17:34:05

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 17:34:05

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 17:34:05

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: UNITHROID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 17:36:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 17:36:36
Data point term sent to Coder	System	14 Oct 2020 17:35:56
User entered 'Unithroid'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:56

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:56

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Hypothyroidism'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:56

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '50'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:56

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'ug (ug)'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:56

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:56

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'once daily (QD)'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:56

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:56

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Oral (ORAL)'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:56

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:56

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'UN UNK 2018'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:56

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:56

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:56

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:56

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:34:56

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 17:34:56

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 17:34:56

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 17:34:56

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: OTHER ANTI OBESITY DRUGS, PRODUCT: LIRAGLUTIDE, PRODUCTS YNOMY: VICTOZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 04:14:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 04:14:23
Data point term sent to Coder	System	14 Oct 2020 17:36:58
User entered 'Victoza'	Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Leptin resistance (weight control)'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '1.8'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'mg (mg)'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'once daily (QD)'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'UN UNK 2018'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	14 Oct 2020 17:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 17:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 17:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 17:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
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: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Nov 2020 15:21:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 15:21:45
Data point term sent to Coder	System	13 Nov 2020 15:20:54
User entered 'Ibuprofen'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 15:19:55

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Frances Saubon (b) (4)	13 Nov 2020 15:19:55

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:21

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN AND MYALGIA is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN AND MYALGIA did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:47:34
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN AND MYALGIA is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN AND MYALGIA did not meet the AE reporting criteria. ' answered with 'does not meet AE criteria' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	14 Dec 2020 15:09:14

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN AND MYALGIA is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN AND MYALGIA did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 06:45:03
User entered 'Injection site pain and myalgia'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 15:19:55

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '800'	Frances Saubon (b) (4)	13 Nov 2020 15:19:55

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'mg (mg)'	Frances Saubon (b) (4)	13 Nov 2020 15:19:55

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 15:19:55

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'once (ONCE)'	Frances Saubon (b) (4)	13 Nov 2020 15:19:55

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 15:19:55

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Oral (ORAL)'	Frances Saubon (b) (4)	13 Nov 2020 15:19:55

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 15:19:55

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '11 Nov 2020'	Frances Saubon (b) (4)	13 Nov 2020 15:19:55

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Frances Saubon (b) (4)	13 Nov 2020 15:19:55

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Frances Saubon (b) (4)	13 Nov 2020 15:19:55

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '11 Nov 2020'	Frances Saubon (b) (4)	13 Nov 2020 15:19:55

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Frances Saubon (b) (4)	13 Nov 2020 15:19:55

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:44
User entered empty.	System	13 Nov 2020 15:19:55

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:44
User entered empty.	System	13 Nov 2020 15:19:55

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:44
User entered empty.	System	13 Nov 2020 15:19:55

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
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)	13 Nov 2020 15:23:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 15:23:45
Data point term sent to Coder	System	13 Nov 2020 15:22:55
User entered 'Acetaminophen'	Frances Saubon (b) (4)	13 Nov 2020 15:22:35

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Frances Saubon (b) (4)	13 Nov 2020 15:22:35

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User closed query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:47:40
Query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf. ' answered with 'does not meet AE criteria, patient reported it to us on a safety call' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	14 Dec 2020 15:09:44
User opened query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 06:45:28
User entered 'Fever'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 15:22:35

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '1000'	Frances Saubon (b) (4)	13 Nov 2020 15:22:35

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'mg (mg)'	Frances Saubon (b) (4)	13 Nov 2020 15:22:35

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 15:22:35

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'once (ONCE)'	Frances Saubon (b) (4)	13 Nov 2020 15:22:35

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 15:22:35

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Oral (ORAL)'	Frances Saubon (b) (4)	13 Nov 2020 15:22:35

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 15:22:35

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:21

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '11 Nov 2020'	Frances Saubon (b) (4)	13 Nov 2020 15:22:35

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Frances Saubon (b) (4)	13 Nov 2020 15:22:35

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Frances Saubon (b) (4)	13 Nov 2020 15:22:35

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '11 Nov 2020'	Frances Saubon (b) (4)	13 Nov 2020 15:22:35

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Frances Saubon (b) (4)	13 Nov 2020 15:22:35

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:47
User entered empty.	System	13 Nov 2020 15:22:35

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:47
User entered empty.	System	13 Nov 2020 15:22:35

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:47
User entered empty.	System	13 Nov 2020 15:22:35

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
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: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Nov 2020 15:24:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 15:24:46
Data point term sent to Coder	System	13 Nov 2020 15:23:56
User entered 'Ibuprofen'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 15:23:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Frances Saubon (b) (4)	13 Nov 2020 15:23:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:47:44
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' answered with 'does not meet AE reporting criteria' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	14 Dec 2020 15:10:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '400'	Frances Saubon (b) (4)	13 Nov 2020 15:23:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'mg (mg)'	Frances Saubon (b) (4)	13 Nov 2020 15:23:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 15:23:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'once (ONCE)'	Frances Saubon (b) (4)	13 Nov 2020 15:23:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 15:23:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Oral (ORAL)'	Frances Saubon (b) (4)	13 Nov 2020 15:23:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Frances Saubon (b) (4)	13 Nov 2020 15:23:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '12 Nov 2020'	Frances Saubon (b) (4)	13 Nov 2020 15:23:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '0'	Frances Saubon (b) (4)	13 Nov 2020 15:23:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'No (N)'	Frances Saubon (b) (4)	13 Nov 2020 15:23:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '12 Nov 2020'	Frances Saubon (b) (4)	13 Nov 2020 15:23:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	Frances Saubon (b) (4)	13 Nov 2020 15:23:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:50
User entered empty.	System	13 Nov 2020 15:23:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:50
User entered empty.	System	13 Nov 2020 15:23:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:50
User entered empty.	System	13 Nov 2020 15:23:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:54
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 03:58:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 03:58:36
Data point term sent to Coder	System	08 Apr 2021 21:38:38
Data point term sent to Coder	System	08 Apr 2021 21:35:33
User entered 'hydromorphone'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:35:31

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:54
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:35
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:35:31

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:54
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:35
User entered 'Gastrointestinal Stromal Tumor' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:37:36
User entered 'Gastrointestinal Stromal Tumor'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:35:31

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:54
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:01:35
User entered '4'	Elisa Moralez (b) (4)	08 Apr 2021 21:35:31

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:54
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:35
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:35:31

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:54
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:35
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:35:31

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:54
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:35
User entered 'as needed (PRN)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:35:31

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:54
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:35
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:35:31

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:54
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:35
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:35:31

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:54
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:35
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:35:31

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:54
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:35
User entered '31 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:35:31

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:54
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:35
User entered '0'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:35:31

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:54
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:35
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:35:31

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:54
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:35
User entered '01 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:35:31

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:54
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:35
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:35:31

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:54
User entered empty.	System	08 Apr 2021 21:35:31

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:54
User entered empty.	System	08 Apr 2021 21:35:31

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:54
User entered empty.	System	08 Apr 2021 21:35:31

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:58
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 04:34:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 04:34:32
Data point term sent to Coder	System	08 Apr 2021 21:37:36
Data point term sent to Coder	System	08 Apr 2021 21:36:35
User entered 'tramadol'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:58
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:29
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:58
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:29
User entered 'Gastrointestinal Stromal Tumor' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:37:28
User entered 'Gastrointestinal Stromal Tumor'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:58
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:46:37
User closed query 'Per source documentation, dose per administration was 50 mg as needed. Please correct or clarify Thank you!' (Site from CRA).		12 Apr 2021 23:46:26
Query 'Per source documentation, dose per administration was 50 mg as needed. Please correct or clarify Thank you!' answered with 'updated, thank you!' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:51:03
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:50:57
User entered '50' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:50:57
User opened query 'Per source documentation, dose per administration was 50 mg as needed. Please correct or clarify Thank you!' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 14:02:54
DataPoint Verified.		09 Apr 2021 14:01:29
User entered '4'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:58
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:29
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:58
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:29
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:58
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:29
User entered 'as needed (PRN)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:58
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:29
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:58
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:29
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:58
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:29
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:58
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:29
User entered '31 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:58
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:29
User entered '0'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:58
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:29
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:36:14
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:58
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:29
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	08 Apr 2021 21:36:14
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	08 Apr 2021 21:36:04
User entered '01 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:58
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:01:29
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:58
User entered empty.	System	08 Apr 2021 21:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:58
User entered empty.	System	08 Apr 2021 21:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:15:58
User entered empty.	System	08 Apr 2021 21:36:04

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:00
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:15
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)	08 Apr 2021 21:38:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 21:38:57
Data point term sent to Coder	System	08 Apr 2021 21:37:35
User entered 'acetaminophen'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:37:10

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:00
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:04:15
User entered 'No (N)'	Elisa Moralez (b) (4)	08 Apr 2021 21:37:10

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:00
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:15
User entered 'Gastrointestinal Stromal Tumor'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:37:10

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:00
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:15
User entered '1000'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:37:10

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:00
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:15
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:37:10

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:00
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:15
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:37:10

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:00
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:46:58
User closed query 'Please confirm frequency. Per source documentation, frequency was 'as needed'. Thank you!' (Site from CRA).		12 Apr 2021 23:46:47
Query 'Please confirm frequency. Per source documentation, frequency was 'as needed'. Thank you!' answered with 'updated, thank you!' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:51:18
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:51:11
User entered 'as needed (PRN)' reason for change:	Elisa Moralez (b) (4)	09 Apr 2021 14:51:11
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:04:15
User opened query 'Please confirm frequency. Per source documentation, frequency was 'as needed'. Thank you!' (Site from CRA).		09 Apr 2021 14:03:42
User entered 'once daily (QD)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:37:10

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:00
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:15
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:37:10

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:00
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:15
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:37:10

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:00
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:15
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:37:10

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:00
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:15
User entered '21 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:37:10

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:00
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:15
User entered '0'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:37:10

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:00
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:15
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:37:10

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:00
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:15
User entered '05 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:37:10

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:00
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:15
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:37:10

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:00
User entered empty.	System	09 Apr 2021 14:51:11
User entered '1'	System	08 Apr 2021 21:37:10

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:00
User entered empty.	System	09 Apr 2021 14:51:11
User entered '1'	System	08 Apr 2021 21:37:10

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:00
User entered empty.	System	09 Apr 2021 14:51:11
User entered '804 (804)'	System	08 Apr 2021 21:37:10

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:07:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:03
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:16
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 22:01:54
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 22:01:54
Data point term sent to Coder	System	08 Apr 2021 21:38:37
User entered 'enoxaparin'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:12

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:07:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:03
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:16
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:12

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:03
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:16
User entered 'Gastrointestinal Stromal Tumor'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:12

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:07:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:03
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:04:16
User entered '40'	Elisa Moralez (b) (4)	08 Apr 2021 21:38:12

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:07:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:03
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:16
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:12

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:07:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:03
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:16
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:12

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:07:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:03
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:16
User entered 'once daily (QD)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:12

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:07:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:03
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:16
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:12

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:07:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:03
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:16
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:12

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:07:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:03
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:16
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:12

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:07:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:03
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:16
User entered '31 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:12

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:03
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:16
User entered '0'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:12

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:03
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:16
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:12

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:03
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:16
User entered '01 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:12

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:07:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:03
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:16
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:12

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:07:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:03
User entered '1'	System	08 Apr 2021 21:38:12

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:03
User entered '1'	System	08 Apr 2021 21:38:12

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:03
User entered '804 (804)'	System	08 Apr 2021 21:38:12

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:07:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:07
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:18
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 04:01:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 04:01:50
Data point term sent to Coder	System	08 Apr 2021 21:39:39
User entered 'ketorolac'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:42

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:07:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:07
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:18
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:42

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:07
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:18
User entered 'Gastrointestinal Stromal Tumor'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:42

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:07:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:07
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:18
User entered '30'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:42

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:07:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:07
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:18
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:42

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:07:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:07
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:18
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:42

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:07:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:07
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:18
User entered 'once daily (QD)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:42

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:07:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:07
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:18
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:42

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:07:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:07
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:18
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:42

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:07:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:07
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:18
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:42

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:07:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:07
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:18
User entered '31 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:42

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:07
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:18
User entered '0'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:42

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:07
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:18
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:42

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:07
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:18
User entered '01 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:42

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:07:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:07
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:18
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:38:42

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:07:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:07
User entered '1'	System	08 Apr 2021 21:38:42

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:07
User entered '1'	System	08 Apr 2021 21:38:42

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:07
User entered '804 (804)'	System	08 Apr 2021 21:38:42

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:07:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:09
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 21:40:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 21:40:57
Data point term sent to Coder	System	08 Apr 2021 21:39:39
User entered 'pantoprazole'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:07:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:09
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:09
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered 'reflux'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:07:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:09
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered '40'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:07:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:09
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:07:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:09
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:07:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:09
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered 'once daily (QD)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:07:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:09
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:07:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:09
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:07:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:09
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:07:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:09
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered '21 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:09
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered '0'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:09
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:09
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered '01 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:07:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:09
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:07:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:09
User entered '1'	System	08 Apr 2021 21:39:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:09
User entered '1'	System	08 Apr 2021 21:39:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:09
User entered '804 (804)'	System	08 Apr 2021 21:39:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:07:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 21:41:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 21:41:59
Data point term sent to Coder	System	08 Apr 2021 21:40:42
User entered 'ondansetron'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:43

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:07:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered 'No (N)'	Elisa Moralez (b) (4)	08 Apr 2021 21:39:43

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered 'nausea and vomiting'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:43

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:07:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered '4'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:43

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:07:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:43

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:07:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:43

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:07:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered 'as needed (PRN)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:43

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:07:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:43

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:07:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:43

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:07:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:43

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:07:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered '31 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:43

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered '0'	Elisa Moralez (b) (4)	08 Apr 2021 21:39:43

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:43

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered '01 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:43

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:07:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:13
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:46
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:39:43

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:07:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:13
User entered empty.	System	08 Apr 2021 21:39:43

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:13
User entered empty.	System	08 Apr 2021 21:39:43

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:13
User entered empty.	System	08 Apr 2021 21:39:43

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:07:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:17
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 04:35:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 04:35:29
Data point term sent to Coder	System	08 Apr 2021 21:40:40
User entered 'promethazine'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:40:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:07:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:17
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:04:45
User entered 'No (N)'	Elisa Moralez (b) (4)	08 Apr 2021 21:40:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:17
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:45
User entered 'Nausea/ Vomiting'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:40:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:07:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:17
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:45
User entered '12.5'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:40:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:07:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:17
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:45
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:40:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:07:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:17
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:45
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:40:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:07:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:17
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:45
User entered 'as needed (PRN)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:40:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:07:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:17
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:45
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:40:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:07:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:17
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:45
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:40:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:07:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:17
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:45
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:40:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:07:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:17
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:45
User entered '31 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:40:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:17
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:45
User entered '0'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:40:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:17
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:45
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:40:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:17
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:45
User entered '01 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:40:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:07:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:17
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:04:45
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:40:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:07:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:17
User entered empty.	System	08 Apr 2021 21:40:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:17
User entered empty.	System	08 Apr 2021 21:40:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:17
User entered empty.	System	08 Apr 2021 21:40:11

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:07:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: BILE AND LIVER THERAPY, ATC: BILE THERAPY, ATC: BILE ACIDS AND DERIVATIVES, PRODUCT: URSODEOXYCHOLIC ACID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Apr 2021 04:34:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 04:34:32
Data point term sent to Coder	System	08 Apr 2021 21:41:43
User entered 'Ursodiol (Urso)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 21:40:48

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:07:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
	(b) (4)	
User entered 'Yes (Y)'	Elisa Morales (b) (4)	08 Apr 2021 21:40:48
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User entered 'prevention of gallstones'	(b) (4) Elisa Morales (b) (4) (b) (4)	08 Apr 2021 21:40:48

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:07:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
	(b) (4)	
User entered '300'	Elisa Morales (b) (4)	08 Apr 2021 21:40:48
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:07:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
	(b) (4)	
User entered 'mg (mg)'	Elisa Morales (b) (4)	08 Apr 2021 21:40:48
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:07:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User entered empty.	(b) (4) Elisa Morales (b) (4)	08 Apr 2021 21:40:48
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:07:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
	(b) (4)	
User entered 'twice daily (BID)'	Elisa Morales (b) (4)	08 Apr 2021 21:40:48
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:07:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
	(b) (4)	
User entered empty.	Elisa Morales (b) (4)	08 Apr 2021 21:40:48
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:07:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
	(b) (4)	
User entered 'Oral (ORAL)'	Elisa Morales (b) (4)	08 Apr 2021 21:40:48
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:07:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User entered empty.	(b) (4) Elisa Morales (b) (4)	08 Apr 2021 21:40:48
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
	(b) (4)	
User entered '12 Jan 2021'	Elisa Morales (b) (4)	08 Apr 2021 21:40:48
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
	(b) (4)	
User entered '0'	Elisa Morales (b) (4)	08 Apr 2021 21:40:48
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
	(b) (4)	
User entered 'Yes (Y)'	Elisa Morales (b) (4)	08 Apr 2021 21:40:48
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
	(b) (4)	
User entered empty.	Elisa Morales (b) (4)	08 Apr 2021 21:40:48
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:07:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User entered 'No (N)'	(b) (4) Elisa Morales (b) (4)	08 Apr 2021 21:40:48
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:07:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Apr 2021 21:40:48

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 21:40:48

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 21:40:48

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:07:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), PRODUCT: SUCRALFATE, PRODUCTSYNONYM: CARAFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 05:45:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 05:45:31
Data point term sent to Coder	System	08 Apr 2021 21:41:43
User entered 'Sucralfate (Carafate)'	Elisa Moralez (b) (4)	08 Apr 2021 21:41:12

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:07:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User entered 'Yes (Y)'	(b) (4) Elisa Morales (b) (4)	08 Apr 2021 21:41:12
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User entered 'prevent ulcers'	(b) (4) Elisa Morales (b) (4)	08 Apr 2021 21:41:12
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:07:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
	(b) (4)	
User entered '1'	Elisa Morales (b) (4)	08 Apr 2021 21:41:12
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:07:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
	(b) (4)	
User entered 'g (g)'	Elisa Morales (b) (4)	08 Apr 2021 21:41:12
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:07:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User entered empty.	(b) (4) Elisa Morales (b) (4)	08 Apr 2021 21:41:12
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:07:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User entered 'four times daily (QID)'	(b) (4) Elisa Morales (b) (4)	08 Apr 2021 21:41:12
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:07:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User entered empty.	(b) (4) Elisa Morales (b) (4)	08 Apr 2021 21:41:12
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:07:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User entered 'Oral (ORAL)'	(b) (4) Elisa Morales (b) (4)	08 Apr 2021 21:41:12
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:07:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User entered empty.	(b) (4) Elisa Morales (b) (4)	08 Apr 2021 21:41:12
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
	(b) (4)	
User entered '12 Jan 2021'	Elisa Morales (b) (4)	08 Apr 2021 21:41:12
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
	(b) (4)	
User entered '0'	Elisa Morales (b) (4)	08 Apr 2021 21:41:12
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4)	08 Apr 2021 21:41:12
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User entered empty.	(b) (4) Elisa Morales (b) (4)	08 Apr 2021 21:41:12
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:07:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User entered 'No (N)'	(b) (4) Elisa Morales (b) (4)	08 Apr 2021 21:41:12
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:07:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Apr 2021 21:41:12

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 21:41:12

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 21:41:12

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:07:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 04:19:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 04:19:38
Data point term sent to Coder	System	08 Apr 2021 21:41:43
User entered 'Omeprazole (Prilosec)'	Elisa Moralez (b) (4)	08 Apr 2021 21:41:36

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:07:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
	(b) (4)	
User entered 'No (N)'	Elisa Morales (b) (4)	08 Apr 2021 21:41:36
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User entered 'treatment of gerd'	(b) (4) Elisa Morales (b) (4)	08 Apr 2021 21:41:36
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:07:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
	(b) (4)	
User entered '40'	Elisa Morales (b) (4)	08 Apr 2021 21:41:36
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:07:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
	(b) (4)	
User entered 'mg (mg)'	Elisa Morales (b) (4)	08 Apr 2021 21:41:36
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:07:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User entered empty.	(b) (4) Elisa Morales (b) (4)	08 Apr 2021 21:41:36
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:07:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User entered 'once daily (QD)'	(b) (4) Elisa Morales (b) (4)	08 Apr 2021 21:41:36
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:07:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
	(b) (4)	
User entered empty.	Elisa Morales (b) (4)	08 Apr 2021 21:41:36
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:07:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User entered 'Oral (ORAL)'	(b) (4) Elisa Morales (b) (4)	08 Apr 2021 21:41:36
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:07:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User entered empty.	(b) (4) Elisa Morales (b) (4)	08 Apr 2021 21:41:36
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User entered '12 Jan 2021'	(b) (4) Elisa Morales (b) (4)	08 Apr 2021 21:41:36
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
	(b) (4)	
User entered '0'	Elisa Morales (b) (4)	08 Apr 2021 21:41:36
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
	(b) (4)	
User entered 'Yes (Y)'	Elisa Morales (b) (4)	08 Apr 2021 21:41:36
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User entered empty.	(b) (4) Elisa Morales (b) (4)	08 Apr 2021 21:41:36
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:07:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:38
User entered 'No (N)'	(b) (4) Elisa Morales (b) (4)	08 Apr 2021 21:41:36
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:07:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 21:41:36

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 21:41:36

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 21:41:36

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:07:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:40:25
User coded data point as ATC: ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS, ATC: ANTIPROTOZOALS, ATC: AGENTS AGAINST LEISHMANIASIS AND TRYPANOSOMIASIS, ATC: NITROIMIDAZOLE DERIVATIVES, PRODUCT: BENZNIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:23:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:23:01
Data point term sent to Coder	System	23 Apr 2021 16:08:22
User entered 'Benznidazole'	Elisa Moralez (b) (4)	23 Apr 2021 16:08:10

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:07:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:40:25
User entered 'No (N)'	(b) (4) Elisa Morales (b) (4)	23 Apr 2021 16:08:10
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:40:25
User entered 'Chagas disease treatment'	(b) (4) Elisa Morales (b) (4)	23 Apr 2021 16:08:10
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:07:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:40:25
User entered '300'	(b) (4) Elisa Morales (b) (4)	23 Apr 2021 16:08:10
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:07:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:40:25
User entered 'mg (mg)'	(b) (4) Elisa Morales (b) (4)	23 Apr 2021 16:08:10
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:07:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:40:25
User entered empty.	(b) (4) Elisa Morales (b) (4)	23 Apr 2021 16:08:10
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:07:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:40:25
User entered 'twice daily (BID)'	(b) (4) Elisa Morales (b) (4)	23 Apr 2021 16:08:10
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:07:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:40:25
User entered empty.	(b) (4) Elisa Morales (b) (4)	23 Apr 2021 16:08:10
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:07:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:40:25
User entered 'Oral (ORAL)'	(b) (4) Elisa Morales (b) (4)	23 Apr 2021 16:08:10
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:07:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:40:25
User entered empty.	(b) (4) Elisa Morales (b) (4)	23 Apr 2021 16:08:10
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:07:21

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:40:25
User entered '20 Apr 2021'	(b) (4) Elisa Morales (b) (4)	23 Apr 2021 16:08:10
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:07:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:40:25
User entered '0'	(b) (4) Elisa Morales (b) (4)	23 Apr 2021 16:08:10
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:07:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:40:25
User entered 'Yes (Y)'	(b) (4) Elisa Morales (b) (4)	23 Apr 2021 16:08:10
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:07:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:40:25
User entered empty.	(b) (4) Elisa Morales (b) (4)	23 Apr 2021 16:08:10
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:07:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:40:25
User entered 'No (N)'	(b) (4) Elisa Morales (b) (4)	23 Apr 2021 16:08:10
	(b) (4)	

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:07:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Apr 2021 16:08:10

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 16:08:10

US3322429

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:07:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 16:08:10

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:07:21

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:32:42
DataPoint Verified.		04 Mar 2021 21:18:07
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 19:33:04

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:07:21

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered '13 Nov 2020'	Elisa Morales (b) (4)	05 Feb 2021 19:33:28
	(b) (4)	

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:07:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Esophagogastroduodenoscopy'	(b) (4) Elisa Morales (b) (4)	05 Feb 2021 19:33:28
	(b) (4)	

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Elisa Moralez (b) (4)	05 Feb 2021 19:33:28
	(b) (4)	

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:07:21

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered empty.	Elisa Morales (b) (4)	05 Feb 2021 19:33:28
	(b) (4)	

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:07:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '20 Nov 2020'	Elisa Moralez (b) (4)	05 Feb 2021 19:33:42

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:07:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'PCR Covid-19 test'	Elisa Moralez (b) (4)	05 Feb 2021 19:33:42

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Diagnostic (DIAGNOSTIC)'	Elisa Moralez (b) (4)	05 Feb 2021 19:33:42

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:07:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	05 Feb 2021 19:33:42

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:07:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '04 Dec 2020'	Elisa Moralez (b) (4)	05 Feb 2021 19:33:59

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:07:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'PCR Covid-19 test'	Elisa Moralez (b) (4)	05 Feb 2021 19:33:59

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Diagnostic (DIAGNOSTIC)'	Elisa Moralez (b) (4)	05 Feb 2021 19:33:59

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:07:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	05 Feb 2021 19:33:59

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:07:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '31 Dec 2020'	Elisa Moralez (b) (4)	05 Feb 2021 19:34:42

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:07:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Gastric Bypass (elective)'	Elisa Moralez (b) (4)	05 Feb 2021 19:34:42

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Medical History (MH)'	Elisa Moralez (b) (4)	05 Feb 2021 19:34:42

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:07:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	05 Feb 2021 19:34:42

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:07:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '08 Jan 2021'	Elisa Moralez (b) (4)	05 Feb 2021 19:34:53

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:07:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Rapid COVID-19 test (Negative)'	Elisa Moralez (b) (4)	05 Feb 2021 19:34:53

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Diagnostic (DIAGNOSTIC)'	Elisa Moralez (b) (4)	05 Feb 2021 19:34:53

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:07:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	05 Feb 2021 19:34:53

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:07:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '13 Jan 2021'	Elisa Moralez (b) (4)	05 Feb 2021 19:35:07

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:07:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Oral COVID-19 test (results pending)'	Elisa Moralez (b) (4)	05 Feb 2021 19:35:07

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Diagnostic (DIAGNOSTIC)'	Elisa Moralez (b) (4)	05 Feb 2021 19:35:07

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:07:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	05 Feb 2021 19:35:07

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:07:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '08 Jan 2021'	Elisa Moralez (b) (4)	05 Feb 2021 19:35:19

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:07:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'CT Scan with contrast (Of lungs)'	Elisa Moralez (b) (4)	05 Feb 2021 19:35:19

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Diagnostic (DIAGNOSTIC)'	Elisa Moralez (b) (4)	05 Feb 2021 19:35:19

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:07:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	05 Feb 2021 19:35:19

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:07:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '31 Dec 2020'	Elisa Moralez (b) (4)	05 Feb 2021 19:35:32

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:07:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'removal of Gastrointestinal Stromal Tumor'	Elisa Moralez (b) (4)	05 Feb 2021 19:35:32

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Elisa Moralez (b) (4)	18 Feb 2021 21:32:24
User entered 'Diagnostic (DIAGNOSTIC)'	Elisa Moralez (b) (4)	05 Feb 2021 19:35:32

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:07:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered empty.	Elisa Moralez (b) (4)	05 Feb 2021 19:35:32

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:07:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:24
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered '25 Feb 2021'	Elisa Moralez (b) (4)	09 Mar 2021 17:58:33

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:07:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:24
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered 'PCR COVID-19 (Nasal Swab test) Negative'	Elisa Moralez (b) (4)	09 Mar 2021 17:58:33

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:24
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered 'Diagnostic (DIAGNOSTIC)'	Elisa Moralez (b) (4)	09 Mar 2021 17:58:33

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:07:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:24
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered empty.	Elisa Moralez (b) (4)	09 Mar 2021 17:58:33

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:07:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered '19 Feb 2021'	Elisa Moralez (b) (4)	09 Mar 2021 17:58:45

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:07:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered 'Suture repair of left lower leg laceration'	Elisa Moralez (b) (4)	09 Mar 2021 17:58:45

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:07:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered 'Adverse Event (AE)'	Elisa Moralez (b) (4)	09 Mar 2021 17:58:45

US3322429

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:07:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
User entered empty.	Elisa Moralez (b) (4)	09 Mar 2021 17:58:45

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (U) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'USA-US060-2021-MRNA-1273-P301000009'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Yes (Y)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'No (N)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'No (N)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Yes (Y)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'No (N)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'No (N)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Yes (Y)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Teresa'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Becker'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered '6550 Mapleridge Street'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Houston'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered '77081'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		19 Feb 2021 15:08:31
User entered 'US'	System	08 Feb 2021 19:33:56

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	26 Feb 2021 15:13:30
User entered '4'	System	26 Feb 2021 15:13:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered '3'	System	22 Feb 2021 14:42:13
User entered '2'	System	19 Feb 2021 15:08:52
User entered '1'	System	08 Feb 2021 19:33:56

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'USA-US060-2021-MRNA-1273-P301000009'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Yes (Y)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'No (N)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'No (N)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Yes (Y)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'No (N)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'No (N)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Yes (Y)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Teresa'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Becker'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered '6550 Mapleridge Street'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Houston'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered '77081'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		19 Feb 2021 15:08:31
User entered 'US'	System	08 Feb 2021 19:33:56

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	26 Feb 2021 15:13:30
User entered '4'	System	26 Feb 2021 15:13:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered '3'	System	22 Feb 2021 14:42:13
User entered '2'	System	19 Feb 2021 15:08:52
User entered '1'	System	08 Feb 2021 19:33:56

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:07:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '08/Feb/2021 13:33'	(b) (4) System	08 Feb 2021 19:33:56

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:07:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		19 Feb 2021 15:08:31
User entered 'I'		08 Feb 2021 19:33:56

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'USA-US060-2021-MRNA-1273-P301000009'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Yes (Y)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'No (N)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'No (N)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Yes (Y)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'No (N)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'No (N)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (o) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Yes (Y)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Teresa'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Becker'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered '6550 Mapleridge Street'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Houston'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered '77081'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		19 Feb 2021 15:08:31
User entered 'US'	System	08 Feb 2021 19:33:56

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	26 Feb 2021 15:13:30
User entered '4'	System	26 Feb 2021 15:13:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered '3'	System	22 Feb 2021 14:42:13
User entered '2'	System	19 Feb 2021 15:08:52
User entered '1'	System	08 Feb 2021 19:33:56

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:07:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '19/Feb/2021 10:08'	(b) (4) System	19 Feb 2021 15:08:52

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:07:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:42:04
User entered '1'		19 Feb 2021 15:08:52

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'USA-US060-2021-MRNA-1273-P301000009'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Yes (Y)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'No (N)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'No (N)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Yes (Y)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'No (N)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'No (N)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Yes (Y)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Teresa'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Becker'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered '6550 Mapleridge Street'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Houston'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered '77081'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		19 Feb 2021 15:08:31
User entered 'US'	System	08 Feb 2021 19:33:56

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	26 Feb 2021 15:13:30
User entered '4'	System	26 Feb 2021 15:13:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered '3'	System	22 Feb 2021 14:42:13
User entered '2'	System	19 Feb 2021 15:08:52
User entered '1'	System	08 Feb 2021 19:33:56

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:07:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered '22/Feb/2021 14:42'	(b) (4) System	22 Feb 2021 14:42:13

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:07:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
Reviewed for Safety.		26 Feb 2021 15:13:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:42:13

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'USA-US060-2021-MRNA-1273-P301000009'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Yes (Y)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'No (N)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'No (N)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Yes (Y)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'No (N)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'No (N)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (o) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Yes (Y)'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Teresa'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Becker'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered '6550 Mapleridge Street'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered 'Houston'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		08 Feb 2021 19:33:35
User entered '77081'	System	08 Feb 2021 19:33:06

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:08:39
Un-reviewed for Safety.		19 Feb 2021 15:08:36
Reviewed for Safety.		19 Feb 2021 15:08:31
User entered 'US'	System	08 Feb 2021 19:33:56

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	26 Feb 2021 15:13:30
User entered '4'	System	26 Feb 2021 15:13:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:15:06
	(b) (4)	
User entered '3'	System	22 Feb 2021 14:42:13
User entered '2'	System	19 Feb 2021 15:08:52
User entered '1'	System	08 Feb 2021 19:33:56

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:07:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:21:01
User entered '26/Feb/2021 10:13'	System	26 Feb 2021 15:13:30

US3322429

Folder: SAE USA-US060-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:07:21

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.	Veronica Fragoso (b) (4)	24 Mar 2021 22:14:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:21:01
User entered 'I'		26 Feb 2021 15:13:30