

US3482240 (Prod: Hope Clinic of The Emory Vaccine Center)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:48:53

All time stamps listed in this document are displayed in GMT

US3482240

Form: Participant Creation

Data signed: (b) (4) 01 Apr 2021 23:29:54

Generated On: 09 Jun 2021 17:48:53

Participant ID

US3482240

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

US3482240

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Date of Birth (MMM yyyy)	(b) (6) 1945
Age	75
Age Units	YEARS
Age (Derived)	75
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 15:35:29

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 15:35:29

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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) 13 Feb 2021 15:35:29

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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) 01 Apr 2021 23:30:15

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Condition	DIABETES
Start date (dd MMM yyyy)	UN UNK 1989
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1989
Start Year (derived)	1989
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 01 Apr 2021 23:30:15

Generated On: 09 Jun 2021 17:48:53

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 01 Apr 2021 23:30:15

Generated On: 09 Jun 2021 17:48:53

Condition	SULFA ALLERGY
Start date (dd MMM yyyy)	UN UNK 1948
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 1948
Start Year (derived)	1948
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 01 Apr 2021 23:30:15

Generated On: 09 Jun 2021 17:48:53

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1960
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 1960
Start Year (derived)	1960
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 01 Apr 2021 23:30:15

Generated On: 09 Jun 2021 17:48:53

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 01 Apr 2021 23:30:15

Generated On: 09 Jun 2021 17:48:53

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 01 Apr 2021 23:30:15

Generated On: 09 Jun 2021 17:48:53

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 01 Apr 2021 23:30:15

Generated On: 09 Jun 2021 17:48:53

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 01 Apr 2021 23:30:15

Generated On: 09 Jun 2021 17:48:53

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 01 Apr 2021 23:30:15

Generated On: 09 Jun 2021 17:48:53

Condition	CHRONIC HYPONATREMIA
Start date (dd MMM yyyy)	14 FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 01 Apr 2021 23:30:15

Generated On: 09 Jun 2021 17:48:53

Condition	SHINGLES
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	04 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:55 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 14:55
Height (<i>xxx.x</i>)	62.5 in
Weight (<i>xxx.x</i>)	174 lb
BMI (<i>xxx.x</i>)	31.38334 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:35:29

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 15:35:29

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 15:35:29

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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	RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

What was the date of randomization? (dd MMM yyyy) 04 SEP 2020

What was the participant's randomization number? 190086

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

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)	4 SEP 2020
Time of assessment (00:00-23:59)	14:55 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 14:55
Temperature (xxx.x)	99.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

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)	4 SEP 2020
Time of assessment (00:00-23:59)	17:13 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 17:13
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

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) 4 SEP 2020

What was the treatment time? (00:00-23:59) 16:39 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 16:39

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 SEP 2020
Collection time (00:00-23:59)	15:43 (24 HR)
Collection date and time (derived)	4 SEP 2020 15:43

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Collection date (dd MMM yyyy)			4 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:45	4 SEP 2020 15:45
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

04 SEP 2020 17:17

PC Open Date & Time

04 SEP 2020 16:59

PC Close Date & Time

04 SEP 2020 19:29

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

PC Time Stamp	04 SEP 2020 20:53
PC Open Date & Time	04 SEP 2020 20:24
PC Close Date & Time	05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:48:53

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

97.9 °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

05 SEP 2020 12:21

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 12:06

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:48:53

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 12:10

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 12:22

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:48:53

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 12:23

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

10 SEP 2020 12:11

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

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

04 SEP 2020 17:19

PC Open Date & Time

04 SEP 2020 16:59

PC Close Date & Time

04 SEP 2020 19:29

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 20:54

PC Open Date & Time

04 SEP 2020 20:24

PC Close Date & Time

05 SEP 2020 11:59

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 12:22

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:48:53

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

06 SEP 2020 12:07

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:48:53

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

07 SEP 2020 12:11

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:48:53

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

08 SEP 2020 12:23

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:48:53

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

09 SEP 2020 12:23

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:48:53

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

10 SEP 2020 12:11

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 17:21
PC Open Date & Time	04 SEP 2020 16:59
PC Close Date & Time	04 SEP 2020 19:29

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 20:55
PC Open Date & Time	04 SEP 2020 20:24
PC Close Date & Time	05 SEP 2020 11:59

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

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 ☒

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

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)

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 12:08
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

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 ☒

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

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 ☒

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 12:26
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

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

60 of 2287

EAB) (1725)

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 12:24
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

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

62 of 2287

EAB) (1725)

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482240

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482240

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482240

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482240

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482240

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482240

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	14:05 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 14:05
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

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)	29 SEP 2020
Time of assessment (00:00-23:59)	15:53 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 15:53
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	49 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3482240

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3482240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 29 SEP 2020

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

Treatment Date and Time (derived) 29 SEP 2020 15:23

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

What was the frequency of the study treatment dosing? ONCE

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

US3482240

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 SEP 2020

Collection time (00:00-23:59)

14:30 (24 HR)

Collection date and time (derived)

29 SEP 2020 14:30

US3482240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Collection date (dd MMM yyyy)			29 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:23	29 SEP 2020 14:23
Nasopharyngeal Swab 2	No		

US3482240

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

29 SEP 2020 16:06

PC Open Date & Time

29 SEP 2020 15:43

PC Close Date & Time

29 SEP 2020 18:13

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.4 °F

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

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

PC Time Stamp	30 SEP 2020 09:51
PC Open Date & Time	29 SEP 2020 19:08
PC Close Date & Time	30 SEP 2020 11:59

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 13:28

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 12:11

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 12:19

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 12:06

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 11:18

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 12:01

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 16:07

PC Open Date & Time

29 SEP 2020 15:43

PC Close Date & Time

29 SEP 2020 18:13

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 09:52

PC Open Date & Time

29 SEP 2020 19:08

PC Close Date & Time

30 SEP 2020 11:59

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 13:29

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 12:12

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 12:19

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 12:07

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 11:18

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 12:02

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 16:07
PC Open Date & Time	29 SEP 2020 15:43
PC Close Date & Time	29 SEP 2020 18:13

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 09:52
PC Open Date & Time	29 SEP 2020 19:08
PC Close Date & Time	30 SEP 2020 11:59

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

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 ☒

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 13:29
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 2287

EAB) (1725)

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

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 ☒

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 12:20
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

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 ☒

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 12:07
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 11:19
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

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 ☒

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 12:02
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3482240

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482240

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482240

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482240

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482240

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482240

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482240

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3482240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3482240

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

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.

US3482240

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 OCT 2020

Collection time (00:00-23:59)

14:12 (24 HR)

Collection date and time (derived)

27 OCT 2020 14:12

US3482240

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:35:29

Generated On: 09 Jun 2021 17:48:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 NOV 2020 14:48:30

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 00:02:46

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 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	22 NOV 2020 00:03:29
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 00:04:38

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 DEC 2020 08:34:00
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 13 DEC 2020 11:04:50

Patient Cloud Open Date & Time 13 DEC 2020 00:01

Patient Cloud Close Date & Time 17 DEC 2020 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 00:03:16

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

27 DEC 2020 00:02:51

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 08:42:06

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 09:14:47

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	18 JAN 2021 12:10:33
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	24 JAN 2021 19:49:02
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 23:10:07

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

07 FEB 2021 12:17:19

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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	14 FEB 2021 09:25:13
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

21 FEB 2021 00:05:25

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

01 MAR 2021 08:40:20

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 00:04:37

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 00:03:13

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 MAR 2021 00:29:17

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 00:11:57

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 09:40:27

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 09:17:46

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 08:23:59

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 00:21:56

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 23:18:20

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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"/>

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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°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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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="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"/>

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 <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"/>

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

Patient Cloud Open Date & Time	15 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 SEP 2021 00:01
Patient Cloud Close Date & Time	09 SEP 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 <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"/>

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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"/>

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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"/>

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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"/>

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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"/>

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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="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"/>

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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°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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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"/>

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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"/>

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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"/>

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 719

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

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

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

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

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

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

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 726

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

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

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

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

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

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

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

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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="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"/>

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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"/>

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3482240

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:48:53

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 08:40:35

US3482240

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:30:15

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:30:15

Generated On: 09 Jun 2021 17:48:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482240

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:29:54

Generated On: 09 Jun 2021 17:48:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482240

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:29:54

Generated On: 09 Jun 2021 17:48:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482240

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:29:54

Generated On: 09 Jun 2021 17:48:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482240

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:29:54

Generated On: 09 Jun 2021 17:48:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482240

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:30:15

Generated On: 09 Jun 2021 17:48:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482240

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:29:54

Generated On: 09 Jun 2021 17:48:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482240

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:30:15

Generated On: 09 Jun 2021 17:48:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3482240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 23:30:15

Generated On: 09 Jun 2021 17:48:53

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3482240

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:30:15

Generated On: 09 Jun 2021 17:48:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 MAR 2021

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

US3482240

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 23:30:15

Generated On: 09 Jun 2021 17:48:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 MAR 2021

Collection time (00:00-23:59)

15:16 (24 HR)

Collection date and time (derived)

16 MAR 2021 15:16

US3482240

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:30:15

Generated On: 09 Jun 2021 17:48:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482240

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482240

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3482240

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:48:53

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"/>

US3482240

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:48:53

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3482240

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

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:29:54

Generated On: 09 Jun 2021 17:48:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3482240

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

Date of updated informed consent (dd MMM yyyy) 07 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 07 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 _____

US3482240

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 23:29:54

Generated On: 09 Jun 2021 17:48:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

7 JAN 2021

Collection time (00:00-23:59)

15:10 (24 HR)

Collection date and time (derived)

7 JAN 2021 15:10

US3482240

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 01 Apr 2021 23:29:54

Generated On: 09 Jun 2021 17:48:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 JAN 2021
Collection time (00:00 - 23:59)	15:13
Collection Date and Time (derived)	7 JAN 2021 15:13

US3482240

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 03:23:09

Generated On: 09 Jun 2021 17:48:53

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3482240

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

AEID	USA-US106-2021-MRNA-1273-P30 1000005
Adverse event	LEFT ARM PAIN
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)	07 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	19 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	23 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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US3482240

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3482240

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

ERYTHEMA OVER AC AREA
AND TENDERNESS AND
INDENTATION. HOWEVER
LIKELY DUE TO CAT SCRATCH
OR BITE. ADMITTED FOR
CELLULITIS AND
HYPONATREMIA. BLOOD
CULTURE POSITIVE FOR
PASTEURELLA

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

US3482240

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

AEID	USA-US106-2021-MRNA-1273-P30 1000005
Adverse event	ACUTE KIDNEY INJURY
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 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	19 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	23 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

AEID

Adverse event

LEFT SHOULDER PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

11 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)

15 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUSPECTED ROTATOR CUFF INJURY FROM LIFTING HEAVY OBJECTS ON 01/11/2021. MRI IS ABSENT OF SEPTIC ARTHRITIS.
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)	0

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Mar 2021 22:31:20

Generated On: 09 Jun 2021 17:48:53

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

Yes ☒

No ☐

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

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

Name of Medication GLUCOSAMINE

Prophylaxis Yes ☒
No ☐

Indication HEALTH PROMOTION

Dose per administration 1500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

	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 FEB 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
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) 12 Apr 2021 16:18:18

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Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

Name of Medication HUMALOG

Prophylaxis Yes ☐
No ☒

Indication DIABETES

Dose per administration 14

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

	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	2000
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

Name of Medication LANTUS

Prophylaxis Yes ☐
No ☒

Indication DIABETES

Dose per administration 38

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

If dose unit is Other, specify UNITS

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) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

	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 2000	
Start date completely unknown	False	
Ongoing?	Yes <input checked="" type="radio"/>	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

Name of Medication	MUPIROCIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SKIN INFECTION
Dose per administration	2
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	%
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input checked="" type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication URINARY RETENTION

Dose per administration 0.4

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 (7)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 112

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

Name of Medication MOBIC

Prophylaxis Yes ☐
No ☒

Indication ARTHRITIS

Dose per administration 15

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

3 TIMES PER WEEK

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

Name of Medication SILDENAFIL

Prophylaxis Yes ☐
No ☒

Indication ERECTILE DYSFUNCTION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☐
No ☒

Indication HEALTH PROMOTION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

	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)	UN UNK 2000	
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"/>

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication ARTHRITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

Name of Medication FEXOFENADINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 180

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) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication 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)

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

Name of Medication SEASONAL INFLUENZA
VACCINE

Prophylaxis Yes ☒
No ☐

Indication VACCINATION

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication ARTHRITIS MUSCLE SORENESS

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

	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)	19 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

Name of Medication	TYLENOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	LEFT ARM AND SHOULDER PAIN
Dose per administration	500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

PRODUCTION RELEASE (v12.003
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

	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)	7 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

Name of Medication SODIUM CHLORIDE SOLUTION

Prophylaxis Yes ☐
No ☒

Indication ACUTE KIDNEY INJURY

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input checked="" type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		22 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"/>

US3482240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Mar 2021 22:31:20

Generated On: 09 Jun 2021 17:48:53

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3482240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Mar 2021 22:31:20

Generated On: 09 Jun 2021 17:48:53

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
22 JAN 2021	MRI	Diagnostic	

US3482240

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:48:53

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

US3482240

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:48:53

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 ☐

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

SAEID	USA-US106-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

SAEID	USA-US106-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/JAN/2021 21:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

SAEID	USA-US106-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	25/JAN/2021 15:34
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

SAEID	USA-US106-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	19/FEB/2021 16:03
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

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

SAEID	USA-US106-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	17/MAR/2021 14:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 12 Apr 2021 16:18:18

Generated On: 09 Jun 2021 17:48:53

SAEID	USA-US106-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/APR/2021 06:23
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

US3482240 (Prod: Hope Clinic of The Emory Vaccine Center)

US3482240

Form: Participant Creation

Generated On: 09 Jun 2021 17:48:53

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
User entered 'US3482240'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 18:34:35

US3482240

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:43:04

US3482240

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '04 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 18:34:36

US3482240

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

[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 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Clinic (Clinic)'	Michele McCullough (b) (4)	04 Sep 2020 22:43:04

US3482240

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered 'SCRN'	System	04 Sep 2020 22:43:04

US3482240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:48:53

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered (b) (6) 1945'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 18:34:37

US3482240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:48:53

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '75'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:43:33

US3482240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:48:53

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered 'YEARS'	System	04 Sep 2020 22:43:33

US3482240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:48:53

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered '75'	System	04 Sep 2020 21:15:41

US3482240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:48:53

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Male (M)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:43:33

US3482240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:48:53

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:43:33

US3482240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:48:53

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'I'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:43:33

US3482240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:48:53

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Michele McCullough (b) (4)	04 Sep 2020 22:43:33

US3482240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:48:53

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:43:33

US3482240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:48:53

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Michele McCullough (b) (4)	04 Sep 2020 22:43:33

US3482240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:48:53

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Michele McCullough (b) (4)	04 Sep 2020 22:43:33

US3482240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:48:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:43:33

US3482240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:48:53

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough	04 Sep 2020 22:43:33
	(b) (4)	

US3482240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:48:53

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Michele McCullough (b) (4)	04 Sep 2020 22:43:33

US3482240

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:48:53

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Michele McCullough (b) (4)	04 Sep 2020 22:43:33

US3482240

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:48:53

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '4 Sep 2020'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 21:15:41

US3482240

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered 'Sep 2020'	System	04 Sep 2020 21:15:41

US3482240

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered '2020'	System	04 Sep 2020 21:15:41

US3482240

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:48:53

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Amendment 3 (3)'	Michele McCullough (b) (4)	04 Sep 2020 21:15:41

US3482240

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 21:15:41

US3482240

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:48:53

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 21:15:41

US3482240

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:48:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 21:15:41

US3482240

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:48:53

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 21:15:41

US3482240

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:48:53

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 18:34:36

US3482240

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:48:53

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered 'I'	System	04 Sep 2020 21:15:48

US3482240

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	Michele McCullough (b) (4)	04 Sep 2020 21:15:48

US3482240

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:48:53

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:43:41

US3482240

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:48:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Sep 2020 22:46:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:46:52
Data point term sent to Coder	System	04 Sep 2020 22:45:11
User entered 'diabetes'	Michele McCullough (b) (4)	04 Sep 2020 22:44:43

US3482240

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'un UNK 1989'	Michele McCullough (b) (4)	04 Sep 2020 22:44:43

US3482240

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:48:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Michele McCullough (b) (4)	04 Sep 2020 22:44:43

US3482240

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:48:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:44:43

US3482240

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:44:43

US3482240

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:48:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Michele McCullough (b) (4)	04 Sep 2020 22:44:43

US3482240

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered 'Jan 1989'	System	04 Sep 2020 22:44:43

US3482240

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered '1989'	System	04 Sep 2020 22:44:43

US3482240

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered empty.	System	04 Sep 2020 22:44:43

US3482240

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered empty.	System	04 Sep 2020 22:44:43

US3482240

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:48:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:46:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:46:52
Data point term sent to Coder	System	04 Sep 2020 22:45:11
User entered 'hypertension'	Michele McCullough (b) (4)	04 Sep 2020 22:45:08

US3482240

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'un UNK 2012'	Michele McCullough (b) (4)	04 Sep 2020 22:45:08

US3482240

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:48:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Michele McCullough (b) (4)	04 Sep 2020 22:45:08

US3482240

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:48:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:45:08

US3482240

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	Michele McCullough (b) (4)	04 Sep 2020 22:45:08

US3482240

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:48:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Michele McCullough (b) (4)	04 Sep 2020 22:45:08

US3482240

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered 'Jan 2012'	System	04 Sep 2020 22:45:08

US3482240

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered '2012'	System	04 Sep 2020 22:45:08

US3482240

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered empty.	System	04 Sep 2020 22:45:08

US3482240

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered empty.	System	04 Sep 2020 22:45:08

US3482240

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:48:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:46:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:46:52
Data point term sent to Coder	System	04 Sep 2020 22:46:12
User entered 'sulfa allergy'	Michele McCullough (b) (4)	04 Sep 2020 22:45:29

US3482240

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'un UNK 1948'	Michele McCullough (b) (4)	04 Sep 2020 22:45:29

US3482240

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:48:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:45:29

US3482240

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:48:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:45:29

US3482240

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:45:29

US3482240

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:48:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Michele McCullough (b) (4)	04 Sep 2020 22:45:29

US3482240

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered 'Jan 1948'	System	04 Sep 2020 22:45:29

US3482240

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered '1948'	System	04 Sep 2020 22:45:29

US3482240

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered empty.	System	04 Sep 2020 22:45:29

US3482240

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered empty.	System	04 Sep 2020 22:45:29

US3482240

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:48:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Sep 2020 22:46:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:46:52
Data point term sent to Coder	System	04 Sep 2020 22:46:11
User entered 'seasonal allergies'	Michele McCullough (b) (4)	04 Sep 2020 22:45:55

US3482240

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'un UNK 1960'	Michele McCullough (b) (4)	04 Sep 2020 22:45:55

US3482240

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:48:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Michele McCullough (b) (4)	04 Sep 2020 22:45:55

US3482240

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:48:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:45:55

US3482240

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:45:55

US3482240

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:48:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Michele McCullough (b) (4)	04 Sep 2020 22:45:55

US3482240

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered 'Jan 1960'	System	04 Sep 2020 22:45:55

US3482240

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered '1960'	System	04 Sep 2020 22:45:55

US3482240

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered empty.	System	04 Sep 2020 22:45:55

US3482240

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered empty.	System	04 Sep 2020 22:45:55

US3482240

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:48:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary retention, LLT: Urinary retention - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Sep 2020 22:48:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:48:41
Data point term sent to Coder	System	04 Sep 2020 22:47:13
User entered 'urinary retention'	Michele McCullough (b) (4)	04 Sep 2020 22:46:15

US3482240

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'un UNK 2010'	Michele McCullough (b) (4)	04 Sep 2020 22:46:15

US3482240

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:48:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Michele McCullough (b) (4)	04 Sep 2020 22:46:15

US3482240

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:48:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:46:15

US3482240

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	Michele McCullough (b) (4)	04 Sep 2020 22:46:15

US3482240

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:48:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Michele McCullough (b) (4)	04 Sep 2020 22:46:15

US3482240

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered 'Jan 2010'	System	04 Sep 2020 22:46:15

US3482240

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered '2010'	System	04 Sep 2020 22:46:15

US3482240

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered empty.	System	04 Sep 2020 22:46:15

US3482240

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered empty.	System	04 Sep 2020 22:46:15

US3482240

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:48:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User coded data point as SOC: Reproductive system and breast disorders, HLG: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:48:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:48:41
Data point term sent to Coder	System	04 Sep 2020 22:47:13
User entered 'erectile dysfunction'	Michele McCullough (b) (4)	04 Sep 2020 22:46:43

US3482240

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'un UNK 2015'	Michele McCullough (b) (4)	04 Sep 2020 22:46:43

US3482240

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:48:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Michele McCullough (b) (4)	04 Sep 2020 22:46:43

US3482240

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:48:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:46:43

US3482240

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	Michele McCullough (b) (4)	04 Sep 2020 22:46:43

US3482240

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:48:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Michele McCullough (b) (4)	04 Sep 2020 22:46:43

US3482240

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered 'Jan 2015'	System	04 Sep 2020 22:46:43

US3482240

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered '2015'	System	04 Sep 2020 22:46:43

US3482240

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered empty.	System	04 Sep 2020 22:46:43

US3482240

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered empty.	System	04 Sep 2020 22:46:43

US3482240

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:48:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Sep 2020 22:48:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:48:41
Data point term sent to Coder	System	04 Sep 2020 22:47:13
User entered 'GERD'	Michele McCullough (b) (4)	04 Sep 2020 22:47:00

US3482240

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'un UNK 2015'	Michele McCullough (b) (4)	04 Sep 2020 22:47:00

US3482240

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:48:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Michele McCullough (b) (4)	04 Sep 2020 22:47:00

US3482240

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:48:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:47:00

US3482240

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	Michele McCullough (b) (4)	04 Sep 2020 22:47:00

US3482240

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:48:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Michele McCullough (b) (4)	04 Sep 2020 22:47:00

US3482240

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered 'Jan 2015'	System	04 Sep 2020 22:47:00

US3482240

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered '2015'	System	04 Sep 2020 22:47:00

US3482240

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered empty.	System	04 Sep 2020 22:47:00

US3482240

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered empty.	System	04 Sep 2020 22:47:00

US3482240

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:48:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
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)	04 Sep 2020 22:49:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:49:41
Data point term sent to Coder	System	04 Sep 2020 22:48:13
User entered 'hypothyroidism'	Michele McCullough (b) (4)	04 Sep 2020 22:47:37

US3482240

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'un UNK 2016'	Michele McCullough (b) (4)	04 Sep 2020 22:47:37

US3482240

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:48:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Michele McCullough (b) (4)	04 Sep 2020 22:47:37

US3482240

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:48:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:47:37

US3482240

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:47:37

US3482240

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:48:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:47:37

US3482240

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered 'Jan 2016'	System	04 Sep 2020 22:47:37

US3482240

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered '2016'	System	04 Sep 2020 22:47:37

US3482240

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered empty.	System	04 Sep 2020 22:47:37

US3482240

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered empty.	System	04 Sep 2020 22:47:37

US3482240

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:48:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthritis, PT: Osteoarthritis, LLT: Hand osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 15:10:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 15:10:54
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 09:32:47
Data point term sent to Coder	System	21 Oct 2020 19:57:15
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Michele McCullough (b) (4)	21 Oct 2020 19:56:51
Coding entries removed.	Michele McCullough (b) (4)	21 Oct 2020 19:56:45
User entered 'OSTEOARTHRITIS in both hands' reason for change: New Information	Michele McCullough (b) (4)	21 Oct 2020 19:56:45
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 08:20:28
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 19:44:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 19:44:45

US3482240

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:48:53

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	18 Sep 2020 19:44:06
User entered 'arthritis'	Michele McCullough	18 Sep 2020 19:43:23
	(b) (4)	

US3482240

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'un UNK 2010'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:43:23

US3482240

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:48:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Michele McCullough (b) (4)	18 Sep 2020 19:43:23

US3482240

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:48:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:43:23

US3482240

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	Michele McCullough (b) (4)	18 Sep 2020 19:43:23

US3482240

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:48:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	(b) (4) Michele McCullough	18 Sep 2020 19:43:23
	(b) (4)	

US3482240

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered 'Jan 2010'	System	18 Sep 2020 19:43:23

US3482240

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered '2010'	System	18 Sep 2020 19:43:23

US3482240

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered empty.	System	18 Sep 2020 19:43:23

US3482240

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered empty.	System	18 Sep 2020 19:43:23

US3482240

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:48:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Jan 2021 12:37:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Jan 2021 12:37:57
Data point term sent to Coder	System	22 Jan 2021 18:21:25
User entered 'CHRONIC HYPONATREMIA'	Joy Winters (b) (4)	22 Jan 2021 18:20:56
reason for change: Data Entry Error	(b) (4)	
User entered 'Hyponatremia'	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:20:33

US3482240

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '14 Feb 2020'	Joy Winters (b) (4)	22 Jan 2021 18:20:33

US3482240

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:48:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Joy Winters (b) (4)	22 Jan 2021 18:20:33

US3482240

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:48:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	Joy Winters (b) (4)	22 Jan 2021 18:20:33

US3482240

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	Joy Winters (b) (4)	22 Jan 2021 18:20:33

US3482240

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:48:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Joy Winters (b) (4)	22 Jan 2021 18:20:33

US3482240

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered 'Feb 2020'	System	22 Jan 2021 18:20:33

US3482240

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered '2020'	System	22 Jan 2021 18:20:33

US3482240

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered empty.	System	22 Jan 2021 18:20:33

US3482240

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered empty.	System	22 Jan 2021 18:20:33

US3482240

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:48:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Shingles - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Mar 2021 20:07:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 20:07:03
Data point term sent to Coder	System	16 Mar 2021 20:06:17
User entered 'shingles'	(b) (4), (b) (6)	16 Mar 2021 20:06:07

US3482240

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
User entered 'UN UNK 2004'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 20:06:07

US3482240

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:48:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 20:06:07

US3482240

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:48:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 20:06:07

US3482240

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 20:06:07

US3482240

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:48:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 20:06:07

US3482240

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered 'Jan 2004'	System	16 Mar 2021 20:06:07

US3482240

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered '2004'	System	16 Mar 2021 20:06:07

US3482240

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered empty.	System	16 Mar 2021 20:06:07

US3482240

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered empty.	System	16 Mar 2021 20:06:07

US3482240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:48:22

US3482240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User closed query 'Per CDM: Please record the date in the correct format DD MMM YYYY.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:05:45
Query 'Per CDM: Please record the date in the correct format DD MMM YYYY.' answered with 'format updated' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 15:41:11
User entered '04 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:41:04
User opened query 'Per CDM: Please record the date in the correct format DD MMM YYYY.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 13:01:04
User entered '4 Sep 2020'	Michele McCullough (b) (4)	04 Sep 2020 22:48:22

US3482240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '14:55'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:48:22

US3482240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered '04 Sep 2020 14:55'	System	09 Sep 2020 15:41:04
User entered '4 Sep 2020 14:55'	System	04 Sep 2020 22:48:22

US3482240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '62.5' in	(b) (4)	
	Michele McCullough	04 Sep 2020 22:48:22
DataPoint set to visible.	(b) (4)	
	System	04 Sep 2020 21:15:48

US3482240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '174' lb	(b) (4) Michele McCullough	04 Sep 2020 22:48:22
DataPoint set to visible.	(b) (4) System	04 Sep 2020 21:15:48

US3482240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered '31.38334'	System	04 Sep 2020 22:48:22
DataPoint set to visible.	System	04 Sep 2020 21:15:48

US3482240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered 'kg/m2'	System	04 Sep 2020 22:48:22
DataPoint set to visible.	System	04 Sep 2020 21:15:48

US3482240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User closed query 'Per CDM re-query: Response noted; However per CCGs pg 15-16, a response 'Not done' has to be recorded for the fields TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update the fields accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:00:55
Query 'Per CDM re-query: Response noted; However per CCGs pg 15-16, a response 'Not done' has to be recorded for the fields TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update the fields accordingly.' answered with 'updated' (Site from DM).	Michele McCullough (b) (4)	08 Sep 2020 14:41:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Michele McCullough (b) (4)	08 Sep 2020 14:41:33
User opened query 'Per CDM re-query: Response noted; However per CCGs pg 15-16, a response 'Not done' has to be recorded for the fields TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update the fields accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 14:45:46
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 14:45:27
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	Michele McCullough (b) (4)	04 Sep 2020 22:48:27
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 22:48:22
User entered empty.	Michele McCullough (b) (4)	04 Sep 2020 22:48:22

US3482240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:48:22

US3482240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:48:22

US3482240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 14:41:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 14:45:31
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	Michele McCullough (b) (4)	04 Sep 2020 22:48:31
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 22:48:22
User entered empty.	Michele McCullough (b) (4)	04 Sep 2020 22:48:22

US3482240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered 'bpm'	System	08 Sep 2020 14:41:33
User entered empty.	System	04 Sep 2020 22:48:22

US3482240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 14:41:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 14:45:29
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	Michele McCullough (b) (4)	04 Sep 2020 22:48:36
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 22:48:22
User entered empty.	Michele McCullough (b) (4)	04 Sep 2020 22:48:22

US3482240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered 'breaths/min'	System	08 Sep 2020 14:41:33
User entered empty.	System	04 Sep 2020 22:48:22

US3482240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 14:41:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 14:45:32
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	Michele McCullough (b) (4)	04 Sep 2020 22:48:40
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 22:48:22
User entered empty.	Michele McCullough (b) (4)	04 Sep 2020 22:48:22

US3482240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered 'mmHg'	System	08 Sep 2020 14:41:33
User entered empty.	System	04 Sep 2020 22:48:22

US3482240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 14:41:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 14:45:33
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	Michele McCullough (b) (4)	04 Sep 2020 22:48:44
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 22:48:22
User entered empty.	Michele McCullough (b) (4)	04 Sep 2020 22:48:22

US3482240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User entered 'mmHg'	System	08 Sep 2020 14:41:33
User entered empty.	System	04 Sep 2020 22:48:22

US3482240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04

US3482240

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04

US3482240

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:48:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:49:02

US3482240

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:48:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '4 Sep 2020'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:49:02

US3482240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:48:53

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 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:49:56

US3482240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:48:53

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 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:49:56

US3482240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:48:53

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 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:49:56

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:48:53

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 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'No (N)'	Michele McCullough (b) (4)	04 Sep 2020 22:49:56

US3482240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:48:53

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 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:49:56

US3482240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:48:53

[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 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:49:56

US3482240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:48:53

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 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'No (N)'	Michele McCullough (b) (4)	04 Sep 2020 22:49:56

US3482240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:48:53

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 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'No (N)'	Michele McCullough (b) (4)	04 Sep 2020 22:49:56

US3482240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:48:53

[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 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:49:56

US3482240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:48:53

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 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:49:56

US3482240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:48:53

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 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'No (N)'	Michele McCullough (b) (4)	04 Sep 2020 22:49:56

US3482240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:48:53

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:49:56

US3482240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:48:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough	04 Sep 2020 22:49:56
	(b) (4)	

US3482240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:48:53

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:49:56

US3482240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Michele McCullough (b) (4)	04 Sep 2020 22:49:56

US3482240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:48:53

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 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	Michele McCullough (b) (4)	04 Sep 2020 22:49:56

US3482240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:48:53

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 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:49:56

US3482240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:48:53

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 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:49:56

US3482240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '0'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:49:56

US3482240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:48:53

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'I'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:49:56

US3482240

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:48:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:36:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'resident in a community with ongoing person to person transmission'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:49:56

US3482240

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:50:09

US3482240

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '04 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:53:10
User entered '4 Sep 2020'	Michele McCullough (b) (4)	04 Sep 2020 22:50:09

US3482240

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Clinic (Clinic)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:50:09

US3482240

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User entered 'VISIT1'	System	04 Sep 2020 22:50:09

US3482240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '04 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 20:04:32

US3482240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '190086'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 20:04:32

US3482240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 20:04:32

US3482240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:48:53

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:51:05

US3482240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:48:53

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:51:05

US3482240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:51:05

US3482240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:48:53

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:51:05

US3482240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:48:53

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:51:05

US3482240

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'No (N)'	(b) (4) Michele McCullough	30 Sep 2020 16:01:59
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 05:28:16
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:28:15

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:48:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:02:15
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'updated to ND' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 16:40:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 16:40:25
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:08:53
User entered empty.	Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:48:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:40:25
User entered empty.	Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:48:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:02:15
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'updated to ND' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 16:40:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 16:40:25
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:08:53
User entered empty.	Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:48:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:40:25
User entered empty.	Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User accepted default value 'Pre-Dose (PREDOSE)'	Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '4 Sep 2020'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '14:55'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User entered '4 Sep 2020 14:55'	System	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '99.2' F	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Oral (Oral)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '58'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User entered 'bpm'	System	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '14'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User entered 'breaths/min'	System	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '142'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User entered 'mmHg'	System	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '78'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User entered 'mmHg'	System	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:48:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:02:15
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'updated to ND' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 16:40:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 16:40:25
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:08:53
User entered empty.	Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:48:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:40:25
User entered empty.	Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User accepted default value 'Post-Dose (POSTDOSE)'	Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '4 Sep 2020'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '17:13'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User entered '4 Sep 2020 17:13'	System	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '98.9' F	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Oral (Oral)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '54'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User entered 'bpm'	System	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '16'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User entered 'breaths/min'	System	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '149'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User entered 'mmHg'	System	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '72'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User entered 'mmHg'	System	04 Sep 2020 22:53:17

US3482240

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:48:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:53:47

US3482240

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:48:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:53:47

US3482240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:48:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 21:16:18

US3482240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:48:53

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough	04 Sep 2020 21:16:18
	(b) (4)	

US3482240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough	04 Sep 2020 21:16:18
	(b) (4)	

US3482240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:48:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 21:16:18

US3482240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:48:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '4 Sep 2020'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 21:16:18

US3482240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:48:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '16:39'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 21:16:18

US3482240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:48:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User entered '4 Sep 2020 16:39'	System	04 Sep 2020 21:16:18

US3482240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:48:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Left Arm (LEFT ARM)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 21:16:18

US3482240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:48:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User entered 'ONCE'	System	04 Sep 2020 21:16:18

US3482240

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:48:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 21:16:18

US3482240

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:48:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:54:14

US3482240

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:48:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '4 Sep 2020'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:54:14

US3482240

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:48:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '15:43'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:54:14

US3482240

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:48:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User entered '4 Sep 2020 15:43'	System	04 Sep 2020 22:54:14

US3482240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:48:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '4 Sep 2020'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:54:28

US3482240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:48:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Michele McCullough (b) (4)	04 Sep 2020 22:54:28

US3482240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:48:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:54:28

US3482240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:48:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '15:45'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:54:28

US3482240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:48:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User entered '4 Sep 2020 15:45'	System	04 Sep 2020 22:54:28

US3482240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:48:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Michele McCullough (b) (4)	04 Sep 2020 22:54:28

US3482240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:48:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:54:28

US3482240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:48:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:54:28

US3482240

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:48:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User entered empty.	System	04 Sep 2020 22:54:28

US3482240

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	04 Sep 2020 22:54:38

US3482240

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User entered 'I'	System	04 Sep 2020 22:54:38

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T17:17:25', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '186ed548-d36c-4b7e-85f0-45d1876a777f'	System	04 Sep 2020 21:17:59
User entered 'Yes (Y)'	System	04 Sep 2020 21:17:59

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T17:17:37', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '186ed548-d36c-4b7e-85f0-45d1876a777f'	System	04 Sep 2020 21:17:59
User entered '98.9'	System	04 Sep 2020 21:17:59

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T17:17:46', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '186ed548-d36c-4b7e-85f0-45d1876a777f'	System	04 Sep 2020 21:17:59
User entered 'No (N)'	System	04 Sep 2020 21:17:59

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T17:17:56', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '186ed548-d36c-4b7e-85f0-45d1876a777f'	System	04 Sep 2020 21:17:59
User entered '04 Sep 2020 17:17'	System	04 Sep 2020 21:17:59

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '04 Sep 2020 16:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '04 Sep 2020 19:29'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T20:53:01', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'bc430303-3e06-41d7-b3b7-5d9f3b27d300'	System	05 Sep 2020 00:53:49
User entered 'Yes (Y)'	System	05 Sep 2020 00:53:49

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T20:53:28', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'bc430303-3e06-41d7-b3b7-5d9f3b27d300'	System	05 Sep 2020 00:53:49
User entered '97.8'	System	05 Sep 2020 00:53:49

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T20:53:34', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'bc430303-3e06-41d7-b3b7-5d9f3b27d300'	System	05 Sep 2020 00:53:49
User entered 'No (N)'	System	05 Sep 2020 00:53:49

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T20:53:46', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'bc430303-3e06-41d7-b3b7-5d9f3b27d300'	System	05 Sep 2020 00:53:49
User entered '04 Sep 2020 20:53'	System	05 Sep 2020 00:53:49

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '04 Sep 2020 20:24'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 2'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:48:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-05T12:21:08', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e2908689-9ebf-4be9-9b12-dc3de85cb9bd'	System	05 Sep 2020 16:21:58
User entered 'Yes (Y)'	System	05 Sep 2020 16:21:58

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:48:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-05T12:21:41', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e2908689-9ebf-4be9-9b12-dc3de85cb9bd'	System	05 Sep 2020 16:21:58
User entered '97.9'	System	05 Sep 2020 16:21:58

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-05T12:21:47', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e2908689-9ebf-4be9-9b12-dc3de85cb9bd'	System	05 Sep 2020 16:21:58
User entered 'No (N)'	System	05 Sep 2020 16:21:58

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-05T12:21:54', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e2908689-9ebf-4be9-9b12-dc3de85cb9bd'	System	05 Sep 2020 16:21:58
User entered '05 Sep 2020 12:21'	System	05 Sep 2020 16:21:58

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 3'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:48:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-06T12:06:26', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '6373473b-3003-450e-949a-d8988da2e511'	System	06 Sep 2020 16:06:46
User entered 'Yes (Y)'	System	06 Sep 2020 16:06:46

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:48:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-06T12:06:33', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '6373473b-3003-450e-949a-d8988da2e511'	System	06 Sep 2020 16:06:46
User entered '97.3'	System	06 Sep 2020 16:06:46

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-06T12:06:38', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '6373473b-3003-450e-949a-d8988da2e511'	System	06 Sep 2020 16:06:46
User entered 'No (N)'	System	06 Sep 2020 16:06:46

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-06T12:06:43', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '6373473b-3003-450e-949a-d8988da2e511'	System	06 Sep 2020 16:06:46
User entered '06 Sep 2020 12:06'	System	06 Sep 2020 16:06:46

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 4'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:48:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-07T12:09:54', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '62456fb3-e1a7-47ff-afb4-8d4bc5432891'	System	07 Sep 2020 16:10:15
User entered 'Yes (Y)'	System	07 Sep 2020 16:10:15

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:48:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-07T12:10:02', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '62456fb3-e1a7-47ff-afb4-8d4bc5432891' User entered '97.7'	System	07 Sep 2020 16:10:15
	System	07 Sep 2020 16:10:15

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-07T12:10:06', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '62456fb3-e1a7-47ff-afb4-8d4bc5432891'	System	07 Sep 2020 16:10:15
User entered 'No (N)'	System	07 Sep 2020 16:10:15

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-07T12:10:12', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '62456fb3-e1a7-47ff-afb4-8d4bc5432891'	System	07 Sep 2020 16:10:15
User entered '07 Sep 2020 12:10'	System	07 Sep 2020 16:10:15

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 5'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:48:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-08T12:22:28', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8c83b274-34c8-40e8-97a9-ed07ac6b76cc'	System	08 Sep 2020 16:22:50
User entered 'Yes (Y)'	System	08 Sep 2020 16:22:50

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:48:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-08T12:22:37', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8c83b274-34c8-40e8-97a9-ed07ac6b76cc'	System	08 Sep 2020 16:22:50
User entered '97.4'	System	08 Sep 2020 16:22:50

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-08T12:22:42', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8c83b274-34c8-40e8-97a9-ed07ac6b76cc'	System	08 Sep 2020 16:22:50
User entered 'No (N)'	System	08 Sep 2020 16:22:50

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-08T12:22:47', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8c83b274-34c8-40e8-97a9-ed07ac6b76cc'	System	08 Sep 2020 16:22:50
User entered '08 Sep 2020 12:22'	System	08 Sep 2020 16:22:50

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 6'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:48:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-09T12:23:04', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c1f2a05b-8af3-4f11-85bf-67439eed1cb7'	System	09 Sep 2020 16:23:26
User entered 'Yes (Y)'	System	09 Sep 2020 16:23:26

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:48:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-09T12:23:14', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c1f2a05b-8af3-4f11-85bf-67439eed1cb7' User entered '97.3'	System	09 Sep 2020 16:23:26
	System	09 Sep 2020 16:23:26

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-09T12:23:18', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c1f2a05b-8af3-4f11-85bf-67439eed1cb7'	System	09 Sep 2020 16:23:26
User entered 'No (N)'	System	09 Sep 2020 16:23:26

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-09T12:23:22', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c1f2a05b-8af3-4f11-85bf-67439eed1cb7'	System	09 Sep 2020 16:23:26
User entered '09 Sep 2020 12:23'	System	09 Sep 2020 16:23:26

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 7'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:48:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-10T12:10:55', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'd778b130-0696-4297-9457-30fa07187887'	System	10 Sep 2020 16:11:14
User entered 'Yes (Y)'	System	10 Sep 2020 16:11:14

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:48:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-10T12:11:03', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'd778b130-0696-4297-9457-30fa07187887' User entered '97.0'	System	10 Sep 2020 16:11:14
	System	10 Sep 2020 16:11:14

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-10T12:11:07', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'd778b130-0696-4297-9457-30fa07187887'	System	10 Sep 2020 16:11:14
User entered 'No (N)'	System	10 Sep 2020 16:11:14

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-10T12:11:11', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'd778b130-0696-4297-9457-30fa07187887'	System	10 Sep 2020 16:11:14
User entered '10 Sep 2020 12:11'	System	10 Sep 2020 16:11:14

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T17:18:06', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '85b1dc56-4c81-46f5-8d3f-650d5da11ce7'	System	04 Sep 2020 21:19:42
User entered 'None (1)'	System	04 Sep 2020 21:19:42

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T17:18:24', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '85b1dc56-4c81-46f5-8d3f-650d5da11ce7'	System	04 Sep 2020 21:19:42
User entered 'No (N)'	System	04 Sep 2020 21:19:42

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T17:18:33', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '85b1dc56-4c81-46f5-8d3f-650d5da11ce7'	System	04 Sep 2020 21:19:42
User entered 'No (N)'	System	04 Sep 2020 21:19:42

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T17:19:30', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '85b1dc56-4c81-46f5-8d3f-650d5da11ce7'	System	04 Sep 2020 21:19:42
User entered 'None (1)'	System	04 Sep 2020 21:19:42

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T17:19:40', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '85b1dc56-4c81-46f5-8d3f-650d5da11ce7'	System	04 Sep 2020 21:19:42
User entered '04 Sep 2020 17:19'	System	04 Sep 2020 21:19:42

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '04 Sep 2020 16:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '04 Sep 2020 19:29'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T20:54:01', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'a7bfb4cc-e21b-49b9-8408-71b7246ecdc2'	System	05 Sep 2020 00:54:48
User entered 'None (1)'	System	05 Sep 2020 00:54:48

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T20:54:06', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'a7bfb4cc-e21b-49b9-8408-71b7246ecdc2'	System	05 Sep 2020 00:54:48
User entered 'No (N)'	System	05 Sep 2020 00:54:48

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T20:54:12', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'a7bfb4cc-e21b-49b9-8408-71b7246ecdc2'	System	05 Sep 2020 00:54:48
User entered 'No (N)'	System	05 Sep 2020 00:54:48

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T20:54:38', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'a7bfb4cc-e21b-49b9-8408-71b7246ecdc2'	System	05 Sep 2020 00:54:48
User entered 'None (1)'	System	05 Sep 2020 00:54:48

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T20:54:45', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'a7bfb4cc-e21b-49b9-8408-71b7246ecdc2'	System	05 Sep 2020 00:54:48
User entered '04 Sep 2020 20:54'	System	05 Sep 2020 00:54:48

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '04 Sep 2020 20:24'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 2'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-05T12:22:10', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '38e6022a-c2ac-4100-a04c-ff0417d71981'	System	05 Sep 2020 16:22:58
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 16:22:58

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-05T12:22:14', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '38e6022a-c2ac-4100-a04c-ff0417d71981'	System	05 Sep 2020 16:22:58
User entered 'No (N)'	System	05 Sep 2020 16:22:58

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-05T12:22:25', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '38e6022a-c2ac-4100-a04c-ff0417d71981'	System	05 Sep 2020 16:22:58
User entered 'No (N)'	System	05 Sep 2020 16:22:58

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-05T12:22:47', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '38e6022a-c2ac-4100-a04c-ff0417d71981'	System	05 Sep 2020 16:22:58
User entered 'None (1)'	System	05 Sep 2020 16:22:58

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-05T12:22:56', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '38e6022a-c2ac-4100-a04c-ff0417d71981'	System	05 Sep 2020 16:22:58
User entered '05 Sep 2020 12:22'	System	05 Sep 2020 16:22:58

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 3'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-06T12:07:15', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'cfed6505-8f74-41c5-b92e-2b00a9af08f0'	System	06 Sep 2020 16:07:42
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 16:07:42

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:48:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-06T12:07:19', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'cfed6505-8f74-41c5-b92e-2b00a9af08f0'	System	06 Sep 2020 16:07:42
User entered 'No (N)'	System	06 Sep 2020 16:07:42

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-06T12:07:24', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'cfed6505-8f74-41c5-b92e-2b00a9af08f0'	System	06 Sep 2020 16:07:42
User entered 'No (N)'	System	06 Sep 2020 16:07:42

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-06T12:07:33', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'cfed6505-8f74-41c5-b92e-2b00a9af08f0'	System	06 Sep 2020 16:07:42
User entered 'None (1)'	System	06 Sep 2020 16:07:42

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-06T12:07:39', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'cfed6505-8f74-41c5-b92e-2b00a9af08f0'	System	06 Sep 2020 16:07:42
User entered '06 Sep 2020 12:07'	System	06 Sep 2020 16:07:42

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 4'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-07T12:11:01', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9399fe54-c558-4f13-8fe3-5f1c1c2533c1'	System	07 Sep 2020 16:11:44
User entered 'None (1)'	System	07 Sep 2020 16:11:44

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-07T12:11:08', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9399fe54-c558-4f13-8fe3-5f1c1c2533c1'	System	07 Sep 2020 16:11:44
User entered 'No (N)'	System	07 Sep 2020 16:11:44

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-07T12:11:23', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9399fe54-c558-4f13-8fe3-5f1c1c2533c1'	System	07 Sep 2020 16:11:44
User entered 'No (N)'	System	07 Sep 2020 16:11:44

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-07T12:11:36', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9399fe54-c558-4f13-8fe3-5f1c1c2533c1'	System	07 Sep 2020 16:11:44
User entered 'None (1)'	System	07 Sep 2020 16:11:44

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-07T12:11:41', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9399fe54-c558-4f13-8fe3-5f1c1c2533c1'	System	07 Sep 2020 16:11:44
User entered '07 Sep 2020 12:11'	System	07 Sep 2020 16:11:44

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 5'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-08T12:23:06', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '3f55473f-8bc4-4a26-a4c9-df89642a0c64'	System	08 Sep 2020 16:23:58
User entered 'None (1)'	System	08 Sep 2020 16:23:58

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-08T12:23:29', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '3f55473f-8bc4-4a26-a4c9-df89642a0c64'	System	08 Sep 2020 16:23:58
User entered 'No (N)'	System	08 Sep 2020 16:23:58

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-08T12:23:34', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '3f55473f-8bc4-4a26-a4c9-df89642a0c64'	System	08 Sep 2020 16:23:58
User entered 'No (N)'	System	08 Sep 2020 16:23:58

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-08T12:23:44', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '3f55473f-8bc4-4a26-a4c9-df89642a0c64'	System	08 Sep 2020 16:23:58
User entered 'None (1)'	System	08 Sep 2020 16:23:58

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-08T12:23:54', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '3f55473f-8bc4-4a26-a4c9-df89642a0c64'	System	08 Sep 2020 16:23:58
User entered '08 Sep 2020 12:23'	System	08 Sep 2020 16:23:58

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 6'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-09T12:23:42', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8a459b50-cc30-4db4-992d-102b7797d9e3'	System	09 Sep 2020 16:24:00
User entered 'None (1)'	System	09 Sep 2020 16:24:00

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:48:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-09T12:23:45', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8a459b50-cc30-4db4-992d-102b7797d9e3'	System	09 Sep 2020 16:24:00
User entered 'No (N)'	System	09 Sep 2020 16:24:00

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-09T12:23:49', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8a459b50-cc30-4db4-992d-102b7797d9e3'	System	09 Sep 2020 16:24:00
User entered 'No (N)'	System	09 Sep 2020 16:24:00

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-09T12:23:52', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8a459b50-cc30-4db4-992d-102b7797d9e3'	System	09 Sep 2020 16:24:00
User entered 'None (1)'	System	09 Sep 2020 16:24:00

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-09T12:23:56', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8a459b50-cc30-4db4-992d-102b7797d9e3'	System	09 Sep 2020 16:24:00
User entered '09 Sep 2020 12:23'	System	09 Sep 2020 16:24:00

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 7'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-10T12:11:19', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '055b4634-b4e4-4808-a1d4-c3db0c87b13f'	System	10 Sep 2020 16:11:39
User entered 'None (1)'	System	10 Sep 2020 16:11:39

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:48:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-10T12:11:23', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '055b4634-b4e4-4808-a1d4-c3db0c87b13f'	System	10 Sep 2020 16:11:39
User entered 'No (N)'	System	10 Sep 2020 16:11:39

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-10T12:11:27', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '055b4634-b4e4-4808-a1d4-c3db0c87b13f'	System	10 Sep 2020 16:11:39
User entered 'No (N)'	System	10 Sep 2020 16:11:39

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-10T12:11:32', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '055b4634-b4e4-4808-a1d4-c3db0c87b13f'	System	10 Sep 2020 16:11:39
User entered 'None (1)'	System	10 Sep 2020 16:11:39

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-10T12:11:36', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '055b4634-b4e4-4808-a1d4-c3db0c87b13f' User entered '10 Sep 2020 12:11'	System	10 Sep 2020 16:11:39
	System	10 Sep 2020 16:11:39

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T17:20:06', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c6a1e075-7e48-4d48-98c6-83a1435adce3'	System	04 Sep 2020 21:21:04
User entered 'None (0)'	System	04 Sep 2020 21:21:04

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T17:20:13', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c6a1e075-7e48-4d48-98c6-83a1435adce3'	System	04 Sep 2020 21:21:04
User entered 'None (0)'	System	04 Sep 2020 21:21:04

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T17:20:22', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c6a1e075-7e48-4d48-98c6-83a1435adce3'	System	04 Sep 2020 21:21:04
User entered 'None (0)'	System	04 Sep 2020 21:21:04

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T17:20:27', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c6a1e075-7e48-4d48-98c6-83a1435adce3'	System	04 Sep 2020 21:21:04
User entered 'None (0)'	System	04 Sep 2020 21:21:04

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T17:20:33', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c6a1e075-7e48-4d48-98c6-83a1435adce3'	System	04 Sep 2020 21:21:04
User entered 'None (0)'	System	04 Sep 2020 21:21:04

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T17:20:41', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c6a1e075-7e48-4d48-98c6-83a1435adce3'	System	04 Sep 2020 21:21:04
User entered 'None (0)'	System	04 Sep 2020 21:21:04

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

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)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T17:20:55', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c6a1e075-7e48-4d48-98c6-83a1435adce3'	System	04 Sep 2020 21:21:04
User entered 'No (N)'	System	04 Sep 2020 21:21:04

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T17:21:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c6a1e075-7e48-4d48-98c6-83a1435adce3'	System	04 Sep 2020 21:21:04
User entered '04 Sep 2020 17:21'	System	04 Sep 2020 21:21:04

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '04 Sep 2020 16:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '04 Sep 2020 19:29'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T20:54:57', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'fb49a817-23b4-4731-8cb4-18de137b6c8f'	System	05 Sep 2020 00:55:37
User entered 'None (0)'	System	05 Sep 2020 00:55:37

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T20:55:03', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'fb49a817-23b4-4731-8cb4-18de137b6c8f'	System	05 Sep 2020 00:55:37
User entered 'None (0)'	System	05 Sep 2020 00:55:37

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T20:55:08', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'fb49a817-23b4-4731-8cb4-18de137b6c8f' User entered 'None (0)'	System	05 Sep 2020 00:55:37
	System	05 Sep 2020 00:55:37

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T20:55:12', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'fb49a817-23b4-4731-8cb4-18de137b6c8f' User entered 'None (0)'	System	05 Sep 2020 00:55:37
	System	05 Sep 2020 00:55:37

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T20:55:15', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'fb49a817-23b4-4731-8cb4-18de137b6c8f' User entered 'None (0)'	System	05 Sep 2020 00:55:37
	System	05 Sep 2020 00:55:37

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T20:55:19', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'fb49a817-23b4-4731-8cb4-18de137b6c8f' User entered 'None (0)'	System	05 Sep 2020 00:55:37
	System	05 Sep 2020 00:55:37

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

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)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T20:55:25', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'fb49a817-23b4-4731-8cb4-18de137b6c8f'	System	05 Sep 2020 00:55:37
User entered 'No (N)'	System	05 Sep 2020 00:55:37

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-04T20:55:32', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'fb49a817-23b4-4731-8cb4-18de137b6c8f'	System	05 Sep 2020 00:55:37
User entered '04 Sep 2020 20:55'	System	05 Sep 2020 00:55:37

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '04 Sep 2020 20:24'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 2'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-05T12:19:07', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'd9c598ba-3914-42c3-86a6-b08c4976be6b'	System	05 Sep 2020 16:20:35
User entered 'None (0)'	System	05 Sep 2020 16:20:35

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-05T12:19:12', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'd9c598ba-3914-42c3-86a6-b08c4976be6b'	System	05 Sep 2020 16:20:35
User entered 'None (0)'	System	05 Sep 2020 16:20:35

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-05T12:19:24', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'd9c598ba-3914-42c3-86a6-b08c4976be6b'	System	05 Sep 2020 16:20:35
User entered 'None (0)'	System	05 Sep 2020 16:20:35

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-05T12:19:38', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'd9c598ba-3914-42c3-86a6-b08c4976be6b'	System	05 Sep 2020 16:20:35
User entered 'None (0)'	System	05 Sep 2020 16:20:35

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-05T12:19:41', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'd9c598ba-3914-42c3-86a6-b08c4976be6b'	System	05 Sep 2020 16:20:35
User entered 'None (0)'	System	05 Sep 2020 16:20:35

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-05T12:19:44', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'd9c598ba-3914-42c3-86a6-b08c4976be6b'	System	05 Sep 2020 16:20:35
User entered 'None (0)'	System	05 Sep 2020 16:20:35

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

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)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-05T12:20:15', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'd9c598ba-3914-42c3-86a6-b08c4976be6b'	System	05 Sep 2020 16:20:35
User entered 'No (N)'	System	05 Sep 2020 16:20:35

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-05T12:20:32', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'd9c598ba-3914-42c3-86a6-b08c4976be6b'	System	05 Sep 2020 16:20:35
User entered '05 Sep 2020 12:20'	System	05 Sep 2020 16:20:35

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 3'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-06T12:07:47', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '1bf7b20a-d681-42ab-852e-7cecd23e782d'	System	06 Sep 2020 16:08:17
User entered 'None (0)'	System	06 Sep 2020 16:08:17

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-06T12:07:50', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '1bf7b20a-d681-42ab-852e-7cecd23e782d'	System	06 Sep 2020 16:08:17
User entered 'None (0)'	System	06 Sep 2020 16:08:17

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-06T12:07:55', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '1bf7b20a-d681-42ab-852e-7cecd23e782d'	System	06 Sep 2020 16:08:17
User entered 'None (0)'	System	06 Sep 2020 16:08:17

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-06T12:07:57', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '1bf7b20a-d681-42ab-852e-7cecd23e782d'	System	06 Sep 2020 16:08:17
User entered 'None (0)'	System	06 Sep 2020 16:08:17

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-06T12:08:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '1bf7b20a-d681-42ab-852e-7cecd23e782d'	System	06 Sep 2020 16:08:17
User entered 'None (0)'	System	06 Sep 2020 16:08:17

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-06T12:08:02', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '1bf7b20a-d681-42ab-852e-7cecd23e782d'	System	06 Sep 2020 16:08:17
User entered 'None (0)'	System	06 Sep 2020 16:08:17

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

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)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-06T12:08:05', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '1bf7b20a-d681-42ab-852e-7cecd23e782d'	System	06 Sep 2020 16:08:17
User entered 'No (N)'	System	06 Sep 2020 16:08:17

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-06T12:08:12', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '1bf7b20a-d681-42ab-852e-7cecd23e782d'	System	06 Sep 2020 16:08:17
User entered '06 Sep 2020 12:08'	System	06 Sep 2020 16:08:17

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 4'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-07T12:11:47', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'dae2646f-5f12-4df4-bddf-ac42a99ae648'	System	07 Sep 2020 16:12:14
User entered 'None (0)'	System	07 Sep 2020 16:12:14

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-07T12:11:50', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'dae2646f-5f12-4df4-bddf-ac42a99ae648'	System	07 Sep 2020 16:12:14
User entered 'None (0)'	System	07 Sep 2020 16:12:14

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-07T12:11:53', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'dae2646f-5f12-4df4-bddf-ac42a99ae648'	System	07 Sep 2020 16:12:14
User entered 'None (0)'	System	07 Sep 2020 16:12:14

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-07T12:11:59', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'dae2646f-5f12-4df4-bddf-ac42a99ae648'	System	07 Sep 2020 16:12:14
User entered 'None (0)'	System	07 Sep 2020 16:12:14

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-07T12:12:01', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'dae2646f-5f12-4df4-bddf-ac42a99ae648'	System	07 Sep 2020 16:12:14
User entered 'None (0)'	System	07 Sep 2020 16:12:14

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-07T12:12:03', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'dae2646f-5f12-4df4-bddf-ac42a99ae648'	System	07 Sep 2020 16:12:14
User entered 'None (0)'	System	07 Sep 2020 16:12:14

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

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)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-07T12:12:07', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'dae2646f-5f12-4df4-bddf-ac42a99ae648'	System	07 Sep 2020 16:12:14
User entered 'No (N)'	System	07 Sep 2020 16:12:14

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-07T12:12:12', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'dae2646f-5f12-4df4-bddf-ac42a99ae648'	System	07 Sep 2020 16:12:14
User entered '07 Sep 2020 12:12'	System	07 Sep 2020 16:12:14

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 5'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-08T12:24:53', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '04bbaa39-4e6e-4fef-a79f-91070e710af5'	System	08 Sep 2020 16:26:09
User entered 'None (0)'	System	08 Sep 2020 16:26:09

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-08T12:24:56', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '04bbaa39-4e6e-4fef-a79f-91070e710af5'	System	08 Sep 2020 16:26:09
User entered 'None (0)'	System	08 Sep 2020 16:26:09

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-08T12:25:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '04bbaa39-4e6e-4fef-a79f-91070e710af5'	System	08 Sep 2020 16:26:09
User entered 'None (0)'	System	08 Sep 2020 16:26:09

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-08T12:25:04', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '04bbaa39-4e6e-4fef-a79f-91070e710af5'	System	08 Sep 2020 16:26:09
User entered 'None (0)'	System	08 Sep 2020 16:26:09

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-08T12:25:33', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '04bbaa39-4e6e-4fef-a79f-91070e710af5'	System	08 Sep 2020 16:26:09
User entered 'None (0)'	System	08 Sep 2020 16:26:09

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-08T12:25:37', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '04bbaa39-4e6e-4fef-a79f-91070e710af5'	System	08 Sep 2020 16:26:09
User entered 'None (0)'	System	08 Sep 2020 16:26:09

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

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)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-08T12:25:58', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '04bbaa39-4e6e-4fef-a79f-91070e710af5'	System	08 Sep 2020 16:26:09
User entered 'No (N)'	System	08 Sep 2020 16:26:09

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-08T12:26:05', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '04bbaa39-4e6e-4fef-a79f-91070e710af5'	System	08 Sep 2020 16:26:09
User entered '08 Sep 2020 12:26'	System	08 Sep 2020 16:26:09

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 6'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-09T12:24:03', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '1c80b500-e7e7-42dd-924f-105ec3f17cc4'	System	09 Sep 2020 16:24:29
User entered 'None (0)'	System	09 Sep 2020 16:24:29

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-09T12:24:06', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '1c80b500-e7e7-42dd-924f-105ec3f17cc4'	System	09 Sep 2020 16:24:29
User entered 'None (0)'	System	09 Sep 2020 16:24:29

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-09T12:24:08', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '1c80b500-e7e7-42dd-924f-105ec3f17cc4'	System	09 Sep 2020 16:24:29
User entered 'None (0)'	System	09 Sep 2020 16:24:29

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-09T12:24:12', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '1c80b500-e7e7-42dd-924f-105ec3f17cc4'	System	09 Sep 2020 16:24:29
User entered 'None (0)'	System	09 Sep 2020 16:24:29

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-09T12:24:14', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '1c80b500-e7e7-42dd-924f-105ec3f17cc4'	System	09 Sep 2020 16:24:29
User entered 'None (0)'	System	09 Sep 2020 16:24:29

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-09T12:24:17', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '1c80b500-e7e7-42dd-924f-105ec3f17cc4'	System	09 Sep 2020 16:24:29
User entered 'None (0)'	System	09 Sep 2020 16:24:29

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

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)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-09T12:24:20', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '1c80b500-e7e7-42dd-924f-105ec3f17cc4'	System	09 Sep 2020 16:24:29
User entered 'No (N)'	System	09 Sep 2020 16:24:29

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-09T12:24:26', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '1c80b500-e7e7-42dd-924f-105ec3f17cc4'	System	09 Sep 2020 16:24:29
User entered '09 Sep 2020 12:24'	System	09 Sep 2020 16:24:29

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 7'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-10T12:11:42', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e26dd8c8-68e0-4f9d-a083-ce37e9cc4e72'	System	10 Sep 2020 16:12:10
User entered 'None (0)'	System	10 Sep 2020 16:12:10

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-10T12:11:45', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e26dd8c8-68e0-4f9d-a083-ce37e9cc4e72'	System	10 Sep 2020 16:12:10
User entered 'None (0)'	System	10 Sep 2020 16:12:10

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-10T12:11:48', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e26dd8c8-68e0-4f9d-a083-ce37e9cc4e72'	System	10 Sep 2020 16:12:10
User entered 'None (0)'	System	10 Sep 2020 16:12:10

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-10T12:11:51', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e26dd8c8-68e0-4f9d-a083-ce37e9cc4e72'	System	10 Sep 2020 16:12:10
User entered 'None (0)'	System	10 Sep 2020 16:12:10

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-10T12:11:54', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e26dd8c8-68e0-4f9d-a083-ce37e9cc4e72'	System	10 Sep 2020 16:12:10
User entered 'None (0)'	System	10 Sep 2020 16:12:10

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-10T12:11:56', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e26dd8c8-68e0-4f9d-a083-ce37e9cc4e72'	System	10 Sep 2020 16:12:10
User entered 'None (0)'	System	10 Sep 2020 16:12:10

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

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)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-10T12:11:59', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e26dd8c8-68e0-4f9d-a083-ce37e9cc4e72'	System	10 Sep 2020 16:12:10
User entered 'No (N)'	System	10 Sep 2020 16:12:10

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-10T12:12:04', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e26dd8c8-68e0-4f9d-a083-ce37e9cc4e72'	System	10 Sep 2020 16:12:10
User entered '10 Sep 2020 12:12'	System	10 Sep 2020 16:12:10

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 21:16:18

US3482240

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	11 Sep 2020 16:28:55

US3482240

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '11 Sep 2020'	(b) (4) Michele McCullough (b) (4)	11 Sep 2020 16:28:55

US3482240

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Michele McCullough (b) (4)	11 Sep 2020 16:28:55

US3482240

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	11 Sep 2020 16:28:55

US3482240

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	11 Sep 2020 16:29:02

US3482240

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User entered 'I'	System	11 Sep 2020 16:29:02

US3482240

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 18:12:41

US3482240

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '18 Sep 2020'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 18:12:41

US3482240

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 18:12:41

US3482240

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 18:12:41

US3482240

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 18:12:47

US3482240

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:54:49
User entered 'I'	System	18 Sep 2020 18:12:47

US3482240

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:21:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	25 Sep 2020 19:29:42

US3482240

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:21:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '25 Sep 2020'	(b) (4) Michele McCullough (b) (4)	25 Sep 2020 19:29:42

US3482240

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:21:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Michele McCullough (b) (4)	25 Sep 2020 19:29:42

US3482240

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:21:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough	25 Sep 2020 19:29:42
	(b) (4)	

US3482240

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:21:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	25 Sep 2020 19:29:47

US3482240

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:21:32
User entered 'I'	System	25 Sep 2020 19:29:47

US3482240

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 18:49:13

US3482240

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '29 Sep 2020'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 18:49:13

US3482240

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Clinic (Clinic)'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 18:49:13

US3482240

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered 'VISIT2'	System	29 Sep 2020 18:49:13

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User accepted default value 'Pre-Dose (PREDOSE)'	Michele McCullough (b) (4)	29 Sep 2020 18:50:21

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 18:50:21

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '29 Sep 2020'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 18:50:21

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '14:05'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 18:50:21

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered '29 Sep 2020 14:05'	System	29 Sep 2020 18:50:21

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '98.2' F	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 18:50:21

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Oral (Oral)'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 18:50:21

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough	29 Sep 2020 18:50:21
	(b) (4)	

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '56'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 18:50:21

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered 'bpm'	System	29 Sep 2020 18:50:21

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '16'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 18:50:21

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered 'breaths/min'	System	29 Sep 2020 18:50:21

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '136'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 18:50:21

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered 'mmHg'	System	29 Sep 2020 18:50:21

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '74'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 18:50:21

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:48:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered 'mmHg'	System	29 Sep 2020 18:50:21

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User accepted default value 'Post-Dose (POSTDOSE)'	Michele McCullough (b) (4)	29 Sep 2020 20:47:02

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 20:47:02

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '29 Sep 2020'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 20:47:02

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '15:53'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 20:47:02

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered '29 Sep 2020 15:53'	System	29 Sep 2020 20:47:02

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '98.7' F	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 20:47:02

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Oral (Oral)'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 20:47:02

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 20:47:02

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '49'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 20:47:02

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered 'bpm'	System	29 Sep 2020 20:47:02

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '16'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 20:47:02

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered 'breaths/min'	System	29 Sep 2020 20:47:02

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '152'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 20:47:02

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered 'mmHg'	System	29 Sep 2020 20:47:02

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '80'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 20:47:02

US3482240

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:48:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered 'mmHg'	System	29 Sep 2020 20:47:02

US3482240

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:48:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 18:50:33

US3482240

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:48:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '29 Sep 2020'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 18:50:33

US3482240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:48:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 19:26:35

US3482240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:48:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough	29 Sep 2020 19:26:35
	(b) (4)	

US3482240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough	29 Sep 2020 19:26:35
	(b) (4)	

US3482240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:48:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 19:26:35

US3482240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:48:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '29 Sep 2020'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 19:26:35

US3482240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:48:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '15:23'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 19:26:35

US3482240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:48:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered '29 Sep 2020 15:23'	System	29 Sep 2020 19:26:35

US3482240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:48:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Left Arm (LEFT ARM)'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 19:26:35

US3482240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:48:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered 'ONCE'	System	29 Sep 2020 19:26:35

US3482240

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:48:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 19:26:35

US3482240

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:48:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 18:52:41

US3482240

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:48:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '29 Sep 2020'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 18:52:41

US3482240

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:48:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '14:30'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 18:52:41

US3482240

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:48:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered '29 Sep 2020 14:30'	System	29 Sep 2020 18:52:41

US3482240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:48:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '29 Sep 2020'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 18:53:05

US3482240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:48:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Michele McCullough (b) (4)	29 Sep 2020 18:53:05

US3482240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:48:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 18:53:05

US3482240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:48:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '14:23'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 18:53:05

US3482240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:48:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered '29 Sep 2020 14:23'	System	29 Sep 2020 18:53:05

US3482240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:48:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Michele McCullough (b) (4)	29 Sep 2020 18:53:10

US3482240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:48:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 18:53:10

US3482240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:48:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 18:53:10

US3482240

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:48:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered empty.	System	29 Sep 2020 18:53:10

US3482240

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	29 Sep 2020 20:47:46

US3482240

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered '1'	System	29 Sep 2020 20:47:46

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-29T16:06:22', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '3080c870-e3f3-4a8e-a0a9-c2981d3e4f59'	System	29 Sep 2020 20:06:47
User entered 'Yes (Y)'	System	29 Sep 2020 20:06:47

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-29T16:06:30', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '3080c870-e3f3-4a8e-a0a9-c2981d3e4f59'	System	29 Sep 2020 20:06:47
User entered '98.7'	System	29 Sep 2020 20:06:47

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-29T16:06:38', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '3080c870-e3f3-4a8e-a0a9-c2981d3e4f59'	System	29 Sep 2020 20:06:47
User entered 'No (N)'	System	29 Sep 2020 20:06:47

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-29T16:06:43', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '3080c870-e3f3-4a8e-a0a9-c2981d3e4f59'	System	29 Sep 2020 20:06:47
User entered '29 Sep 2020 16:06'	System	29 Sep 2020 20:06:47

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '29 Sep 2020 15:43'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '29 Sep 2020 18:13'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T09:51:13', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '219f3ab7-9baf-4f01-b36d-95799f4b657a'	System	30 Sep 2020 13:51:39
User entered 'Yes (Y)'	System	30 Sep 2020 13:51:39

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T09:51:21', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '219f3ab7-9baf-4f01-b36d-95799f4b657a'	System	30 Sep 2020 13:51:39
User entered '97.4'	System	30 Sep 2020 13:51:39

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T09:51:26', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '219f3ab7-9baf-4f01-b36d-95799f4b657a'	System	30 Sep 2020 13:51:39
User entered 'No (N)'	System	30 Sep 2020 13:51:39

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T09:51:33', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '219f3ab7-9baf-4f01-b36d-95799f4b657a'	System	30 Sep 2020 13:51:39
User entered '30 Sep 2020 09:51'	System	30 Sep 2020 13:51:39

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '29 Sep 2020 19:08'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 2'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:48:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T13:28:06', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8ea1db92-e6cb-4097-8897-364641388dba'	System	30 Sep 2020 17:28:26
User entered 'Yes (Y)'	System	30 Sep 2020 17:28:26

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:48:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T13:28:13', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8ea1db92-e6cb-4097-8897-364641388dba' User entered '97.5'	System	30 Sep 2020 17:28:26
	System	30 Sep 2020 17:28:26

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T13:28:18', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8ea1db92-e6cb-4097-8897-364641388dba'	System	30 Sep 2020 17:28:26
User entered 'No (N)'	System	30 Sep 2020 17:28:26

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T13:28:24', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8ea1db92-e6cb-4097-8897-364641388dba'	System	30 Sep 2020 17:28:26
User entered '30 Sep 2020 13:28'	System	30 Sep 2020 17:28:26

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 3'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:48:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-01T12:11:10', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'cf40e6e0-a5ca-4a7d-b9ee-27c31f4a726d'	System	01 Oct 2020 16:11:37
User entered 'Yes (Y)'	System	01 Oct 2020 16:11:37

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:48:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-01T12:11:23', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'cf40e6e0-a5ca-4a7d-b9ee-27c31f4a726d'	System	01 Oct 2020 16:11:37
User entered '96.7'	System	01 Oct 2020 16:11:37

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-01T12:11:28', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'cf40e6e0-a5ca-4a7d-b9ee-27c31f4a726d'	System	01 Oct 2020 16:11:37
User entered 'No (N)'	System	01 Oct 2020 16:11:37

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-01T12:11:32', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'cf40e6e0-a5ca-4a7d-b9ee-27c31f4a726d'	System	01 Oct 2020 16:11:37
User entered '01 Oct 2020 12:11'	System	01 Oct 2020 16:11:37

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 4'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:48:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-02T12:18:26', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'ce620e28-b2cd-4d89-b4da-f963df5c04e6'	System	02 Oct 2020 16:19:09
User entered 'Yes (Y)'	System	02 Oct 2020 16:19:09

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:48:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-02T12:18:34', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'ce620e28-b2cd-4d89-b4da-f963df5c04e6'	System	02 Oct 2020 16:19:09
User entered '96.7'	System	02 Oct 2020 16:19:09

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-02T12:19:03', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'ce620e28-b2cd-4d89-b4da-f963df5c04e6'	System	02 Oct 2020 16:19:09
User entered 'No (N)'	System	02 Oct 2020 16:19:09

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-02T12:19:06', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'ce620e28-b2cd-4d89-b4da-f963df5c04e6'	System	02 Oct 2020 16:19:09
User entered '02 Oct 2020 12:19'	System	02 Oct 2020 16:19:09

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 5'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:48:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-03T12:06:44', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'f38e9980-ad6d-4971-9b93-f5ddcf330b88'	System	03 Oct 2020 16:07:03
User entered 'Yes (Y)'	System	03 Oct 2020 16:07:03

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:48:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-03T12:06:52', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'f38e9980-ad6d-4971-9b93-f5ddcf330b88'	System	03 Oct 2020 16:07:03
User entered '97.0'	System	03 Oct 2020 16:07:03

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-03T12:06:55', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'f38e9980-ad6d-4971-9b93-f5ddcf330b88'	System	03 Oct 2020 16:07:03
User entered 'No (N)'	System	03 Oct 2020 16:07:03

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-03T12:06:59', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'f38e9980-ad6d-4971-9b93-f5ddcf330b88'	System	03 Oct 2020 16:07:03
User entered '03 Oct 2020 12:06'	System	03 Oct 2020 16:07:03

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 6'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:48:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T11:17:57', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'eab7b09b-0284-4b84-90a4-c80ddfc29c49'	System	05 Oct 2020 15:18:17
User entered 'Yes (Y)'	System	05 Oct 2020 15:18:17

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:48:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T11:18:07', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'eab7b09b-0284-4b84-90a4-c80ddfc29c49'	System	05 Oct 2020 15:18:17
User entered '97.1'	System	05 Oct 2020 15:18:17

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T11:18:10', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'eab7b09b-0284-4b84-90a4-c80ddfc29c49'	System	05 Oct 2020 15:18:17
User entered 'No (N)'	System	05 Oct 2020 15:18:17

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T11:18:14', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'eab7b09b-0284-4b84-90a4-c80ddfc29c49'	System	05 Oct 2020 15:18:17
User entered '05 Oct 2020 11:18'	System	05 Oct 2020 15:18:17

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 7'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:48:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T12:01:33', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '93a2879a-5a7f-48f4-a8c5-9dfe363dea29'	System	05 Oct 2020 16:02:47
User entered 'Yes (Y)'	System	05 Oct 2020 16:02:47

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:48:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T12:01:40', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '93a2879a-5a7f-48f4-a8c5-9dfe363dea29'	System	05 Oct 2020 16:02:47
User entered '97.1'	System	05 Oct 2020 16:02:47

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T12:01:44', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '93a2879a-5a7f-48f4-a8c5-9dfe363dea29'	System	05 Oct 2020 16:02:47
User entered 'No (N)'	System	05 Oct 2020 16:02:47

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T12:01:47', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '93a2879a-5a7f-48f4-a8c5-9dfe363dea29'	System	05 Oct 2020 16:02:47
User entered '05 Oct 2020 12:01'	System	05 Oct 2020 16:02:47

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-29T16:06:52', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c40fed9c-8cbe-4c99-b635-1e3503aaeed5'	System	29 Sep 2020 20:07:15
User entered 'None (1)'	System	29 Sep 2020 20:07:15

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-29T16:06:56', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c40fed9c-8cbe-4c99-b635-1e3503aaeed5'	System	29 Sep 2020 20:07:15
User entered 'No (N)'	System	29 Sep 2020 20:07:15

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-29T16:07:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c40fed9c-8cbe-4c99-b635-1e3503aaeed5'	System	29 Sep 2020 20:07:15
User entered 'No (N)'	System	29 Sep 2020 20:07:15

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-29T16:07:09', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c40fed9c-8cbe-4c99-b635-1e3503aaeed5'	System	29 Sep 2020 20:07:15
User entered 'None (1)'	System	29 Sep 2020 20:07:15

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-29T16:07:13', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c40fed9c-8cbe-4c99-b635-1e3503aaeed5'	System	29 Sep 2020 20:07:15
User entered '29 Sep 2020 16:07'	System	29 Sep 2020 20:07:15

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '29 Sep 2020 15:43'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '29 Sep 2020 18:13'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T09:51:50', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '4dec157a-a005-4910-9c49-2739b9166ae0'	System	30 Sep 2020 13:52:27
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 13:52:27

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T09:51:56', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '4dec157a-a005-4910-9c49-2739b9166ae0'	System	30 Sep 2020 13:52:27
User entered 'No (N)'	System	30 Sep 2020 13:52:27

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T09:52:11', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '4dec157a-a005-4910-9c49-2739b9166ae0'	System	30 Sep 2020 13:52:27
User entered 'No (N)'	System	30 Sep 2020 13:52:27

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T09:52:20', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '4dec157a-a005-4910-9c49-2739b9166ae0'	System	30 Sep 2020 13:52:27
User entered 'None (1)'	System	30 Sep 2020 13:52:27

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T09:52:24', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '4dec157a-a005-4910-9c49-2739b9166ae0'	System	30 Sep 2020 13:52:27
User entered '30 Sep 2020 09:52'	System	30 Sep 2020 13:52:27

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '29 Sep 2020 19:08'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 2'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T13:28:32', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8eb7dba6-e1bb-4173-b68c-8f3939e8ab3b'	System	30 Sep 2020 17:29:09
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 17:29:09

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:48:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T13:28:43', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8eb7dba6-e1bb-4173-b68c-8f3939e8ab3b'	System	30 Sep 2020 17:29:09
User entered 'No (N)'	System	30 Sep 2020 17:29:09

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T13:28:52', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8eb7dba6-e1bb-4173-b68c-8f3939e8ab3b'	System	30 Sep 2020 17:29:09
User entered 'No (N)'	System	30 Sep 2020 17:29:09

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T13:29:04', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8eb7dba6-e1bb-4173-b68c-8f3939e8ab3b'	System	30 Sep 2020 17:29:09
User entered 'None (1)'	System	30 Sep 2020 17:29:09

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T13:29:07', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8eb7dba6-e1bb-4173-b68c-8f3939e8ab3b'	System	30 Sep 2020 17:29:09
User entered '30 Sep 2020 13:29'	System	30 Sep 2020 17:29:09

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 3'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-01T12:11:39', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'd4e07d01-5afa-4581-a7fd-7028ddc0df2e'	System	01 Oct 2020 16:12:07
User entered 'None (1)'	System	01 Oct 2020 16:12:07

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:48:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-01T12:11:43', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'd4e07d01-5afa-4581-a7fd-7028ddc0df2e'	System	01 Oct 2020 16:12:07
User entered 'No (N)'	System	01 Oct 2020 16:12:07

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-01T12:11:52', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'd4e07d01-5afa-4581-a7fd-7028ddc0df2e'	System	01 Oct 2020 16:12:07
User entered 'No (N)'	System	01 Oct 2020 16:12:07

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-01T12:12:01', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'd4e07d01-5afa-4581-a7fd-7028ddc0df2e'	System	01 Oct 2020 16:12:07
User entered 'None (1)'	System	01 Oct 2020 16:12:07

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-01T12:12:05', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'd4e07d01-5afa-4581-a7fd-7028ddc0df2e'	System	01 Oct 2020 16:12:07
User entered '01 Oct 2020 12:12'	System	01 Oct 2020 16:12:07

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 4'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-02T12:19:11', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '6ba18e2a-6e5d-441d-a09b-9d4d982597d7'	System	02 Oct 2020 16:19:35
User entered 'None (1)'	System	02 Oct 2020 16:19:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:48:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-02T12:19:16', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '6ba18e2a-6e5d-441d-a09b-9d4d982597d7'	System	02 Oct 2020 16:19:35
User entered 'No (N)'	System	02 Oct 2020 16:19:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-02T12:19:19', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '6ba18e2a-6e5d-441d-a09b-9d4d982597d7'	System	02 Oct 2020 16:19:35
User entered 'No (N)'	System	02 Oct 2020 16:19:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-02T12:19:28', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '6ba18e2a-6e5d-441d-a09b-9d4d982597d7'	System	02 Oct 2020 16:19:35
User entered 'None (1)'	System	02 Oct 2020 16:19:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-02T12:19:31', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '6ba18e2a-6e5d-441d-a09b-9d4d982597d7'	System	02 Oct 2020 16:19:35
User entered '02 Oct 2020 12:19'	System	02 Oct 2020 16:19:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 5'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-03T12:07:05', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '718d3045-6121-468b-8d65-1e9a137c11fb'	System	03 Oct 2020 16:07:22
User entered 'None (1)'	System	03 Oct 2020 16:07:22

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:48:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-03T12:07:08', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '718d3045-6121-468b-8d65-1e9a137c11fb'	System	03 Oct 2020 16:07:22
User entered 'No (N)'	System	03 Oct 2020 16:07:22

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-03T12:07:11', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '718d3045-6121-468b-8d65-1e9a137c11fb'	System	03 Oct 2020 16:07:22
User entered 'No (N)'	System	03 Oct 2020 16:07:22

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-03T12:07:13', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '718d3045-6121-468b-8d65-1e9a137c11fb'	System	03 Oct 2020 16:07:22
User entered 'None (1)'	System	03 Oct 2020 16:07:22

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-03T12:07:16', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '718d3045-6121-468b-8d65-1e9a137c11fb'	System	03 Oct 2020 16:07:22
User entered '03 Oct 2020 12:07'	System	03 Oct 2020 16:07:22

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 6'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T11:18:21', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'd484339f-6b1d-4029-a21d-c377d436c315'	System	05 Oct 2020 15:18:38
User entered 'None (1)'	System	05 Oct 2020 15:18:38

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:48:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T11:18:24', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'd484339f-6b1d-4029-a21d-c377d436c315'	System	05 Oct 2020 15:18:38
User entered 'No (N)'	System	05 Oct 2020 15:18:38

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T11:18:27', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'd484339f-6b1d-4029-a21d-c377d436c315'	System	05 Oct 2020 15:18:38
User entered 'No (N)'	System	05 Oct 2020 15:18:38

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T11:18:29', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'd484339f-6b1d-4029-a21d-c377d436c315'	System	05 Oct 2020 15:18:38
User entered 'None (1)'	System	05 Oct 2020 15:18:38

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T11:18:32', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'd484339f-6b1d-4029-a21d-c377d436c315'	System	05 Oct 2020 15:18:38
User entered '05 Oct 2020 11:18'	System	05 Oct 2020 15:18:38

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 7'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T12:01:52', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'fadb75be-40d2-41bd-9e12-80f7897670d7'	System	05 Oct 2020 16:03:01
User entered 'None (1)'	System	05 Oct 2020 16:03:01

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:48:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T12:01:55', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'fadb75be-40d2-41bd-9e12-80f7897670d7'	System	05 Oct 2020 16:03:01
User entered 'No (N)'	System	05 Oct 2020 16:03:01

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T12:01:59', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'fadb75be-40d2-41bd-9e12-80f7897670d7'	System	05 Oct 2020 16:03:01
User entered 'No (N)'	System	05 Oct 2020 16:03:01

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:48:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T12:02:01', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'fadb75be-40d2-41bd-9e12-80f7897670d7'	System	05 Oct 2020 16:03:01
User entered 'None (1)'	System	05 Oct 2020 16:03:01

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:48:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T12:02:05', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'fadb75be-40d2-41bd-9e12-80f7897670d7'	System	05 Oct 2020 16:03:01
User entered '05 Oct 2020 12:02'	System	05 Oct 2020 16:03:01

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-29T16:07:21', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9fc2ec29-d116-4f54-826e-7cc2f16037eb'	System	29 Sep 2020 20:07:49
User entered 'None (0)'	System	29 Sep 2020 20:07:49

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-29T16:07:24', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9fc2ec29-d116-4f54-826e-7cc2f16037eb'	System	29 Sep 2020 20:07:49
User entered 'None (0)'	System	29 Sep 2020 20:07:49

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-29T16:07:27', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9fc2ec29-d116-4f54-826e-7cc2f16037eb'	System	29 Sep 2020 20:07:49
User entered 'None (0)'	System	29 Sep 2020 20:07:49

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-29T16:07:30', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9fc2ec29-d116-4f54-826e-7cc2f16037eb'	System	29 Sep 2020 20:07:49
User entered 'None (0)'	System	29 Sep 2020 20:07:49

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-29T16:07:32', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9fc2ec29-d116-4f54-826e-7cc2f16037eb'	System	29 Sep 2020 20:07:49
User entered 'None (0)'	System	29 Sep 2020 20:07:49

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-29T16:07:34', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9fc2ec29-d116-4f54-826e-7cc2f16037eb'	System	29 Sep 2020 20:07:49
User entered 'None (0)'	System	29 Sep 2020 20:07:49

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

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)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-29T16:07:42', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9fc2ec29-d116-4f54-826e-7cc2f16037eb'	System	29 Sep 2020 20:07:49
User entered 'No (N)'	System	29 Sep 2020 20:07:49

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-29T16:07:47', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9fc2ec29-d116-4f54-826e-7cc2f16037eb'	System	29 Sep 2020 20:07:49
User entered '29 Sep 2020 16:07'	System	29 Sep 2020 20:07:49

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '29 Sep 2020 15:43'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '29 Sep 2020 18:13'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T09:52:32', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '6bf459a5-6359-47a3-a780-23d3150347ec'	System	30 Sep 2020 13:53:00
User entered 'None (0)'	System	30 Sep 2020 13:53:00

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T09:52:34', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '6bf459a5-6359-47a3-a780-23d3150347ec'	System	30 Sep 2020 13:53:00
User entered 'None (0)'	System	30 Sep 2020 13:53:00

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T09:52:41', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '6bf459a5-6359-47a3-a780-23d3150347ec'	System	30 Sep 2020 13:53:00
User entered 'None (0)'	System	30 Sep 2020 13:53:00

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T09:52:44', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '6bf459a5-6359-47a3-a780-23d3150347ec'	System	30 Sep 2020 13:53:00
User entered 'None (0)'	System	30 Sep 2020 13:53:00

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T09:52:47', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '6bf459a5-6359-47a3-a780-23d3150347ec'	System	30 Sep 2020 13:53:00
User entered 'None (0)'	System	30 Sep 2020 13:53:00

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T09:52:49', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '6bf459a5-6359-47a3-a780-23d3150347ec'	System	30 Sep 2020 13:53:00
User entered 'None (0)'	System	30 Sep 2020 13:53:00

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

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)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T09:52:53', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '6bf459a5-6359-47a3-a780-23d3150347ec'	System	30 Sep 2020 13:53:00
User entered 'No (N)'	System	30 Sep 2020 13:53:00

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T09:52:56', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '6bf459a5-6359-47a3-a780-23d3150347ec'	System	30 Sep 2020 13:53:00
User entered '30 Sep 2020 09:52'	System	30 Sep 2020 13:53:00

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '29 Sep 2020 19:08'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 2'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T13:29:14', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'f41dddaf-9b8f-4769-9315-3a2220f54bc5'	System	30 Sep 2020 17:29:45
User entered 'None (0)'	System	30 Sep 2020 17:29:45

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T13:29:17', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'f41dddaf-9b8f-4769-9315-3a2220f54bc5'	System	30 Sep 2020 17:29:45
User entered 'None (0)'	System	30 Sep 2020 17:29:45

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T13:29:23', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'f41dddaf-9b8f-4769-9315-3a2220f54bc5'	System	30 Sep 2020 17:29:45
User entered 'No interference with activity (1)'	System	30 Sep 2020 17:29:45

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T13:29:27', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'f41dddaf-9b8f-4769-9315-3a2220f54bc5'	System	30 Sep 2020 17:29:45
User entered 'None (0)'	System	30 Sep 2020 17:29:45

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T13:29:30', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'f41dddaf-9b8f-4769-9315-3a2220f54bc5'	System	30 Sep 2020 17:29:45
User entered 'None (0)'	System	30 Sep 2020 17:29:45

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T13:29:33', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'f41dddaf-9b8f-4769-9315-3a2220f54bc5'	System	30 Sep 2020 17:29:45
User entered 'None (0)'	System	30 Sep 2020 17:29:45

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

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)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T13:29:36', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'f41dddaf-9b8f-4769-9315-3a2220f54bc5'	System	30 Sep 2020 17:29:45
User entered 'No (N)'	System	30 Sep 2020 17:29:45

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-09-30T13:29:42', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'f41dddaf-9b8f-4769-9315-3a2220f54bc5'	System	30 Sep 2020 17:29:45
User entered '30 Sep 2020 13:29'	System	30 Sep 2020 17:29:45

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 3'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-01T12:12:12', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e031e7eb-94a3-48c6-a122-0ddcd0faaf78'	System	01 Oct 2020 16:12:42
User entered 'None (0)'	System	01 Oct 2020 16:12:42

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-01T12:12:15', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e031e7eb-94a3-48c6-a122-0ddcd0faaf78'	System	01 Oct 2020 16:12:42
User entered 'None (0)'	System	01 Oct 2020 16:12:42

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-01T12:12:23', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e031e7eb-94a3-48c6-a122-0ddcd0faaf78'	System	01 Oct 2020 16:12:42
User entered 'None (0)'	System	01 Oct 2020 16:12:42

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-01T12:12:28', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e031e7eb-94a3-48c6-a122-0ddcd0faaf78'	System	01 Oct 2020 16:12:42
User entered 'None (0)'	System	01 Oct 2020 16:12:42

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-01T12:12:30', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e031e7eb-94a3-48c6-a122-0ddcd0faaf78'	System	01 Oct 2020 16:12:42
User entered 'None (0)'	System	01 Oct 2020 16:12:42

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-01T12:12:33', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e031e7eb-94a3-48c6-a122-0ddcd0faaf78'	System	01 Oct 2020 16:12:42
User entered 'None (0)'	System	01 Oct 2020 16:12:42

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

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)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-01T12:12:36', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e031e7eb-94a3-48c6-a122-0ddcd0faaf78'	System	01 Oct 2020 16:12:42
User entered 'No (N)'	System	01 Oct 2020 16:12:42

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-01T12:12:39', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e031e7eb-94a3-48c6-a122-0ddcd0faaf78'	System	01 Oct 2020 16:12:42
User entered '01 Oct 2020 12:12'	System	01 Oct 2020 16:12:42

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 4'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-02T12:19:37', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '83a86538-a003-4ade-a393-e00501de2450'	System	02 Oct 2020 16:20:20
User entered 'None (0)'	System	02 Oct 2020 16:20:20

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-02T12:19:40', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '83a86538-a003-4ade-a393-e00501de2450'	System	02 Oct 2020 16:20:20
User entered 'None (0)'	System	02 Oct 2020 16:20:20

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-02T12:20:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '83a86538-a003-4ade-a393-e00501de2450'	System	02 Oct 2020 16:20:20
User entered 'None (0)'	System	02 Oct 2020 16:20:20

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-02T12:20:02', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '83a86538-a003-4ade-a393-e00501de2450'	System	02 Oct 2020 16:20:20
User entered 'None (0)'	System	02 Oct 2020 16:20:20

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-02T12:20:05', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '83a86538-a003-4ade-a393-e00501de2450'	System	02 Oct 2020 16:20:20
User entered 'None (0)'	System	02 Oct 2020 16:20:20

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-02T12:20:07', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '83a86538-a003-4ade-a393-e00501de2450'	System	02 Oct 2020 16:20:20
User entered 'None (0)'	System	02 Oct 2020 16:20:20

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

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)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-02T12:20:11', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '83a86538-a003-4ade-a393-e00501de2450'	System	02 Oct 2020 16:20:20
User entered 'No (N)'	System	02 Oct 2020 16:20:20

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-02T12:20:16', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '83a86538-a003-4ade-a393-e00501de2450'	System	02 Oct 2020 16:20:20
User entered '02 Oct 2020 12:20'	System	02 Oct 2020 16:20:20

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 5'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-03T12:07:21', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c05d8ffa-ac3f-4352-a021-cb2732f7766d'	System	03 Oct 2020 16:07:46
User entered 'None (0)'	System	03 Oct 2020 16:07:46

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-03T12:07:23', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c05d8ffa-ac3f-4352-a021-cb2732f7766d'	System	03 Oct 2020 16:07:46
User entered 'None (0)'	System	03 Oct 2020 16:07:46

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-03T12:07:25', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c05d8ffa-ac3f-4352-a021-cb2732f7766d'	System	03 Oct 2020 16:07:46
User entered 'None (0)'	System	03 Oct 2020 16:07:46

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-03T12:07:28', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c05d8ffa-ac3f-4352-a021-cb2732f7766d'	System	03 Oct 2020 16:07:46
User entered 'None (0)'	System	03 Oct 2020 16:07:46

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-03T12:07:30', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c05d8ffa-ac3f-4352-a021-cb2732f7766d'	System	03 Oct 2020 16:07:46
User entered 'None (0)'	System	03 Oct 2020 16:07:46

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-03T12:07:32', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c05d8ffa-ac3f-4352-a021-cb2732f7766d'	System	03 Oct 2020 16:07:46
User entered 'None (0)'	System	03 Oct 2020 16:07:46

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

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)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-03T12:07:38', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c05d8ffa-ac3f-4352-a021-cb2732f7766d'	System	03 Oct 2020 16:07:46
User entered 'No (N)'	System	03 Oct 2020 16:07:46

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-03T12:07:43', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c05d8ffa-ac3f-4352-a021-cb2732f7766d' User entered '03 Oct 2020 12:07'	System	03 Oct 2020 16:07:46
	System	03 Oct 2020 16:07:46

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 6'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T11:18:54', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8e56e39d-5bca-4424-9750-d3e9e63c3e0b'	System	05 Oct 2020 15:19:17
User entered 'None (0)'	System	05 Oct 2020 15:19:17

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T11:18:56', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8e56e39d-5bca-4424-9750-d3e9e63c3e0b'	System	05 Oct 2020 15:19:17
User entered 'None (0)'	System	05 Oct 2020 15:19:17

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T11:18:59', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8e56e39d-5bca-4424-9750-d3e9e63c3e0b'	System	05 Oct 2020 15:19:17
User entered 'None (0)'	System	05 Oct 2020 15:19:17

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T11:19:01', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8e56e39d-5bca-4424-9750-d3e9e63c3e0b'	System	05 Oct 2020 15:19:17
User entered 'None (0)'	System	05 Oct 2020 15:19:17

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T11:19:06', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8e56e39d-5bca-4424-9750-d3e9e63c3e0b'	System	05 Oct 2020 15:19:17
User entered 'None (0)'	System	05 Oct 2020 15:19:17

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T11:19:08', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8e56e39d-5bca-4424-9750-d3e9e63c3e0b'	System	05 Oct 2020 15:19:17
User entered 'None (0)'	System	05 Oct 2020 15:19:17

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

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)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T11:19:11', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8e56e39d-5bca-4424-9750-d3e9e63c3e0b'	System	05 Oct 2020 15:19:17
User entered 'No (N)'	System	05 Oct 2020 15:19:17

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T11:19:14', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8e56e39d-5bca-4424-9750-d3e9e63c3e0b'	System	05 Oct 2020 15:19:17
User entered '05 Oct 2020 11:19'	System	05 Oct 2020 15:19:17

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	29 Sep 2020 19:26:35
User entered 'Day 7'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T12:02:11', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9b116221-b4dd-4289-868d-a1ecac0d897c'	System	05 Oct 2020 16:03:30
User entered 'None (0)'	System	05 Oct 2020 16:03:30

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T12:02:13', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9b116221-b4dd-4289-868d-a1ecac0d897c'	System	05 Oct 2020 16:03:30
User entered 'None (0)'	System	05 Oct 2020 16:03:30

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T12:02:16', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9b116221-b4dd-4289-868d-a1ecac0d897c'	System	05 Oct 2020 16:03:30
User entered 'None (0)'	System	05 Oct 2020 16:03:30

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T12:02:18', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9b116221-b4dd-4289-868d-a1ecac0d897c'	System	05 Oct 2020 16:03:30
User entered 'None (0)'	System	05 Oct 2020 16:03:30

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T12:02:20', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9b116221-b4dd-4289-868d-a1ecac0d897c'	System	05 Oct 2020 16:03:30
User entered 'None (0)'	System	05 Oct 2020 16:03:30

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T12:02:23', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9b116221-b4dd-4289-868d-a1ecac0d897c'	System	05 Oct 2020 16:03:30
User entered 'None (0)'	System	05 Oct 2020 16:03:30

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

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)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T12:02:30', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9b116221-b4dd-4289-868d-a1ecac0d897c'	System	05 Oct 2020 16:03:30
User entered 'No (N)'	System	05 Oct 2020 16:03:30

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-10-05T12:02:33', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9b116221-b4dd-4289-868d-a1ecac0d897c'	System	05 Oct 2020 16:03:30
User entered '05 Oct 2020 12:02'	System	05 Oct 2020 16:03:30

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 19:26:35

US3482240

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:48:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 19:26:35

US3482240

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	07 Oct 2020 20:35:10

US3482240

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:53:24
User entered '7 Oct 2020'	Michele McCullough (b) (4)	07 Oct 2020 20:35:10

US3482240

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Michele McCullough (b) (4)	07 Oct 2020 20:35:10

US3482240

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	07 Oct 2020 20:35:10

US3482240

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	07 Oct 2020 20:35:15

US3482240

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered 'I'	System	07 Oct 2020 20:35:15

US3482240

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:09:36

US3482240

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:09:36

US3482240

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:09:36

US3482240

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:09:36

US3482240

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:09:40

US3482240

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered 'I'	System	13 Oct 2020 19:09:40

US3482240

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	20 Oct 2020 21:21:30

US3482240

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '20 Oct 2020'	(b) (4) Michele McCullough (b) (4)	20 Oct 2020 21:21:30

US3482240

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Michele McCullough (b) (4)	20 Oct 2020 21:21:30

US3482240

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	20 Oct 2020 21:21:30

US3482240

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	20 Oct 2020 21:21:35

US3482240

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered 'I'	System	20 Oct 2020 21:21:35

US3482240

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough	28 Oct 2020 14:13:56
	(b) (4)	

US3482240

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '27 Oct 2020'	(b) (4) Michele McCullough (b) (4)	28 Oct 2020 14:13:56

US3482240

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Clinic (Clinic)'	(b) (4) Michele McCullough (b) (4)	28 Oct 2020 14:13:56

US3482240

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered 'VISIT3'	System	28 Oct 2020 14:13:56

US3482240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	28 Oct 2020 14:14:07

US3482240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	28 Oct 2020 14:14:07

US3482240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	28 Oct 2020 14:14:07

US3482240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered empty.	System	28 Oct 2020 14:14:07

US3482240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough	28 Oct 2020 14:14:07
	(b) (4)	

US3482240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough	28 Oct 2020 14:14:07
	(b) (4)	

US3482240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough	28 Oct 2020 14:14:07
	(b) (4)	

US3482240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	28 Oct 2020 14:14:07

US3482240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered empty.	System	28 Oct 2020 14:14:07

US3482240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	28 Oct 2020 14:14:07

US3482240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered empty.	System	28 Oct 2020 14:14:07

US3482240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	28 Oct 2020 14:14:07

US3482240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered empty.	System	28 Oct 2020 14:14:07

US3482240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough	28 Oct 2020 14:14:07
	(b) (4)	

US3482240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered empty.	System	28 Oct 2020 14:14:07

US3482240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23

US3482240

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23

US3482240

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:48:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	28 Oct 2020 14:14:13

US3482240

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:48:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered empty.	(b) (4) Michele McCullough (b) (4)	28 Oct 2020 14:14:13

US3482240

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:48:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough	28 Oct 2020 14:14:25
	(b) (4)	

US3482240

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:48:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '27 Oct 2020'	(b) (4) Michele McCullough	28 Oct 2020 14:14:25
	(b) (4)	

US3482240

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:48:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered '14:12'	(b) (4) Michele McCullough	28 Oct 2020 14:14:25
	(b) (4)	

US3482240

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:48:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered '27 Oct 2020 14:12'	System	28 Oct 2020 14:14:25

US3482240

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:35:30
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	28 Oct 2020 14:14:36

US3482240

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered 'I'	System	28 Oct 2020 14:14:36

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 64'	System	04 Sep 2020 21:16:18

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14
Data entry locked.	System	04 Sep 2020 21:16:18
User entered '04 Nov 2020 00:01'	System	04 Sep 2020 21:16:18

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14
Data entry locked.	System	04 Sep 2020 21:16:18
User entered '08 Nov 2020 23:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 71'	System	04 Sep 2020 21:16:18

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-11-12T14:48:08', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '217929dd-ec83-4415-8ec8-732a3a14290d'	System	12 Nov 2020 19:48:35
User entered 'No (N)'	System	12 Nov 2020 19:48:35

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-11-12T14:48:18', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '217929dd-ec83-4415-8ec8-732a3a14290d'	System	12 Nov 2020 19:48:35
User entered 'No (N)'	System	12 Nov 2020 19:48:35

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-11-12T14:48:30', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '217929dd-ec83-4415-8ec8-732a3a14290d'	System	12 Nov 2020 19:48:35
User entered '12 Nov 2020 14:48:30'	System	12 Nov 2020 19:48:35

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered '11 Nov 2020 00:01'	System	04 Sep 2020 21:16:18

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered '15 Nov 2020 23:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered 'Day 78'	System	04 Sep 2020 21:16:18

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-11-18T00:02:23', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'a85656ba-3d6c-4d4f-9d96-4c2b7dad9399'	System	18 Nov 2020 05:02:49
User entered 'No (N)'	System	18 Nov 2020 05:02:49

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-11-18T00:02:35', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'a85656ba-3d6c-4d4f-9d96-4c2b7dad9399'	System	18 Nov 2020 05:02:49
User entered 'No (N)'	System	18 Nov 2020 05:02:49

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-11-18T00:02:46', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'a85656ba-3d6c-4d4f-9d96-4c2b7dad9399'	System	18 Nov 2020 05:02:49
User entered '18 Nov 2020 00:02:46'	System	18 Nov 2020 05:02:49

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered '18 Nov 2020 00:01'	System	04 Sep 2020 21:16:18

US3482240

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:46:23
Data entry locked.	System	04 Sep 2020 21:16:18
User entered '22 Nov 2020 23:59'	System	04 Sep 2020 21:16:18

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2020-11-22T00:03:08', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'b637c59e-534b-4a87-90eb-b2a96fb3d493'	System	22 Nov 2020 05:05:06
User entered 'No (N)'	System	22 Nov 2020 05:05:06

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2020-11-22T00:03:17', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'b637c59e-534b-4a87-90eb-b2a96fb3d493'	System	22 Nov 2020 05:05:06
User entered 'No (N)'	System	22 Nov 2020 05:05:06

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-11-22T00:03:29', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'b637c59e-534b-4a87-90eb-b2a96fb3d493'	System	22 Nov 2020 05:05:06
User entered '22 Nov 2020 00:03:29'	System	22 Nov 2020 05:05:06

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2020-11-29T00:04:22', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '4e990d93-6acc-4dc3-9647-c65ffc4ee8fd'	System	29 Nov 2020 05:04:42
User entered 'No (N)'	System	29 Nov 2020 05:04:42

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2020-11-29T00:04:31', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '4e990d93-6acc-4dc3-9647-c65ffc4ee8fd'	System	29 Nov 2020 05:04:42
User entered 'No (N)'	System	29 Nov 2020 05:04:42

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-11-29T00:04:38', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '4e990d93-6acc-4dc3-9647-c65ffc4ee8fd'	System	29 Nov 2020 05:04:42
User entered '29 Nov 2020 00:04:38'	System	29 Nov 2020 05:04:42

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2020-12-06T08:33:37', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '66ce5c47-8e35-4808-b2bb-8c0994243d3e'	System	06 Dec 2020 13:34:03
User entered 'No (N)'	System	06 Dec 2020 13:34:03

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2020-12-06T08:33:50', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '66ce5c47-8e35-4808-b2bb-8c0994243d3e'	System	06 Dec 2020 13:34:03
User entered 'No (N)'	System	06 Dec 2020 13:34:03

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-12-06T08:34:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '66ce5c47-8e35-4808-b2bb-8c0994243d3e'	System	06 Dec 2020 13:34:03
User entered '06 Dec 2020 08:34:00'	System	06 Dec 2020 13:34:03

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2020-12-13T11:04:39', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e43564d9-a410-4e48-b594-653fa429c548'	System	13 Dec 2020 16:04:52
User entered 'No (N)'	System	13 Dec 2020 16:04:52

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2020-12-13T11:04:46', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e43564d9-a410-4e48-b594-653fa429c548'	System	13 Dec 2020 16:04:52
User entered 'No (N)'	System	13 Dec 2020 16:04:52

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-12-13T11:04:50', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e43564d9-a410-4e48-b594-653fa429c548'	System	13 Dec 2020 16:04:52
User entered '13 Dec 2020 11:04:50'	System	13 Dec 2020 16:04:52

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2020-12-20T00:03:07', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '754e2f08-b999-4f58-b06d-c03a696946e1'	System	20 Dec 2020 05:03:19
User entered 'No (N)'	System	20 Dec 2020 05:03:19

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2020-12-20T00:03:12', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '754e2f08-b999-4f58-b06d-c03a696946e1'	System	20 Dec 2020 05:03:19
User entered 'No (N)'	System	20 Dec 2020 05:03:19

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-12-20T00:03:16', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '754e2f08-b999-4f58-b06d-c03a696946e1'	System	20 Dec 2020 05:03:19
User entered '20 Dec 2020 00:03:16'	System	20 Dec 2020 05:03:19

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2020-12-27T00:02:32', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8bc2db7e-ae8b-4343-a5de-56a2b5405d24'	System	27 Dec 2020 05:03:14
User entered 'No (N)'	System	27 Dec 2020 05:03:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2020-12-27T00:02:43', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8bc2db7e-ae8b-4343-a5de-56a2b5405d24'	System	27 Dec 2020 05:03:14
User entered 'No (N)'	System	27 Dec 2020 05:03:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2020-12-27T00:02:51', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8bc2db7e-ae8b-4343-a5de-56a2b5405d24'	System	27 Dec 2020 05:03:14
User entered '27 Dec 2020 00:02:51'	System	27 Dec 2020 05:03:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2021-01-03T08:41:50', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '09ff3000-25d5-4f26-a619-dd9102ad3679'	System	03 Jan 2021 13:42:09
User entered 'No (N)'	System	03 Jan 2021 13:42:09

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2021-01-03T08:41:59', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '09ff3000-25d5-4f26-a619-dd9102ad3679'	System	03 Jan 2021 13:42:09
User entered 'No (N)'	System	03 Jan 2021 13:42:09

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-01-03T08:42:06', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '09ff3000-25d5-4f26-a619-dd9102ad3679'	System	03 Jan 2021 13:42:09
User entered '03 Jan 2021 08:42:06'	System	03 Jan 2021 13:42:09

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2021-01-10T09:14:33', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e5958a6c-5902-4e4e-89be-92081956284a'	System	10 Jan 2021 14:14:49
User entered 'No (N)'	System	10 Jan 2021 14:14:49

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2021-01-10T09:14:42', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e5958a6c-5902-4e4e-89be-92081956284a'	System	10 Jan 2021 14:14:49
User entered 'No (N)'	System	10 Jan 2021 14:14:49

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-01-10T09:14:47', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'e5958a6c-5902-4e4e-89be-92081956284a' User entered '10 Jan 2021 09:14:47'	System	10 Jan 2021 14:14:49

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2021-01-18T12:08:34', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '99f2d209-cc1a-4d66-8b1e-44b83fcf0bdf'	System	18 Jan 2021 17:10:46
User entered 'Yes (Y)'	System	18 Jan 2021 17:10:46

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2021-01-18T12:08:43', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '99f2d209-cc1a-4d66-8b1e-44b83fcf0bdf'	System	18 Jan 2021 17:10:46
User entered 'No (N)'	System	18 Jan 2021 17:10:46

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2021-01-18T12:08:53', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '99f2d209-cc1a-4d66-8b1e-44b83fcf0bdf'	System	18 Jan 2021 17:10:46
User entered 'Yes (Y)'	System	18 Jan 2021 17:10:46

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-01-18T12:09:21', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '99f2d209-cc1a-4d66-8b1e-44b83fcf0bdf'	System	18 Jan 2021 17:10:46
User entered '0'	System	18 Jan 2021 17:10:46

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-01-18T12:09:21', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '99f2d209-cc1a-4d66-8b1e-44b83fcf0bdf'	System	18 Jan 2021 17:10:46
User entered '1'	System	18 Jan 2021 17:10:46

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-01-18T12:09:21', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '99f2d209-cc1a-4d66-8b1e-44b83fcf0bdf'	System	18 Jan 2021 17:10:46
User entered '0'	System	18 Jan 2021 17:10:46

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-01-18T12:09:21', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '99f2d209-cc1a-4d66-8b1e-44b83fcf0bdf'	System	18 Jan 2021 17:10:46
User entered '0'	System	18 Jan 2021 17:10:46

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-01-18T12:09:21', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '99f2d209-cc1a-4d66-8b1e-44b83fcf0bdf'	System	18 Jan 2021 17:10:46
User entered '0'	System	18 Jan 2021 17:10:46

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-01-18T12:09:21', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '99f2d209-cc1a-4d66-8b1e-44b83fcf0bdf'	System	18 Jan 2021 17:10:46
User entered '1'	System	18 Jan 2021 17:10:46

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-01-18T12:09:21', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '99f2d209-cc1a-4d66-8b1e-44b83fcf0bdf'	System	18 Jan 2021 17:10:46
User entered '1'	System	18 Jan 2021 17:10:46

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-01-18T12:09:21', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '99f2d209-cc1a-4d66-8b1e-44b83fcf0bdf'	System	18 Jan 2021 17:10:46
User entered '1'	System	18 Jan 2021 17:10:46

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-01-18T12:09:21', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '99f2d209-cc1a-4d66-8b1e-44b83fcf0bdf'	System	18 Jan 2021 17:10:46
User entered '0'	System	18 Jan 2021 17:10:46

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-01-18T12:09:21', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '99f2d209-cc1a-4d66-8b1e-44b83fcf0bdf'	System	18 Jan 2021 17:10:46
User entered '0'	System	18 Jan 2021 17:10:46

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-01-18T12:09:21', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '99f2d209-cc1a-4d66-8b1e-44b83fcf0bdf'	System	18 Jan 2021 17:10:46
User entered '0'	System	18 Jan 2021 17:10:46

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-01-18T12:09:21', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '99f2d209-cc1a-4d66-8b1e-44b83fcf0bdf'	System	18 Jan 2021 17:10:46
User entered '0'	System	18 Jan 2021 17:10:46

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-01-18T12:09:21', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '99f2d209-cc1a-4d66-8b1e-44b83fcf0bdf'	System	18 Jan 2021 17:10:46
User entered '0'	System	18 Jan 2021 17:10:46

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-01-18T12:09:21', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '99f2d209-cc1a-4d66-8b1e-44b83fcf0bdf'	System	18 Jan 2021 17:10:46
User entered '0'	System	18 Jan 2021 17:10:46

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-01-18T12:09:21', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '99f2d209-cc1a-4d66-8b1e-44b83fcf0bdf'	System	18 Jan 2021 17:10:46
User entered '0'	System	18 Jan 2021 17:10:46

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-01-18T12:09:21', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '99f2d209-cc1a-4d66-8b1e-44b83fcf0bdf'	System	18 Jan 2021 17:10:46
User entered '0'	System	18 Jan 2021 17:10:46

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-01-18T12:09:21', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '99f2d209-cc1a-4d66-8b1e-44b83fcf0bdf'	System	18 Jan 2021 17:10:46
User entered '0'	System	18 Jan 2021 17:10:46

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Please 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 (60a92855f87d290c)', Time: '2021-01-18T12:10:15', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '99f2d209-cc1a-4d66-8b1e-44b83fcf0bdf'	System	18 Jan 2021 17:10:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Jan 2021 17:10:46

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2021-01-18T12:10:26', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '99f2d209-cc1a-4d66-8b1e-44b83fcf0bdf'	System	18 Jan 2021 17:10:46
User entered 'No (N)'	System	18 Jan 2021 17:10:46

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-01-18T12:10:33', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '99f2d209-cc1a-4d66-8b1e-44b83fcf0bdf' User entered '18 Jan 2021 12:10:33'	System	18 Jan 2021 17:10:46
	System	18 Jan 2021 17:10:46

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2021-01-24T19:48:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '0ab54e98-0b2f-4612-b68e-574f2dfdaabe'	System	25 Jan 2021 00:49:13
User entered 'Yes (Y)'	System	25 Jan 2021 00:49:13

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2021-01-24T19:48:09', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '0ab54e98-0b2f-4612-b68e-574f2dfdaabe'	System	25 Jan 2021 00:49:13
User entered 'No (N)'	System	25 Jan 2021 00:49:13

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2021-01-24T19:48:33', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '0ab54e98-0b2f-4612-b68e-574f2dfdaabe'	System	25 Jan 2021 00:49:13
User entered 'No (N)'	System	25 Jan 2021 00:49:13

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2021-01-24T19:48:44', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '0ab54e98-0b2f-4612-b68e-574f2dfdaabe'	System	25 Jan 2021 00:49:13
User entered 'Yes (Y)'	System	25 Jan 2021 00:49:13

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Please 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 (60a92855f87d290c)', Time: '2021-01-24T19:48:57', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '0ab54e98-0b2f-4612-b68e-574f2dfdaabe'	System	25 Jan 2021 00:49:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Jan 2021 00:49:13

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-01-24T19:49:02', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '0ab54e98-0b2f-4612-b68e-574f2dfdaabe'	System	25 Jan 2021 00:49:13
User entered '24 Jan 2021 19:49:02'	System	25 Jan 2021 00:49:13

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2021-01-31T23:10:01', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '6d2f4162-83dd-44e8-808b-7c0b4ced1d5e'	System	01 Feb 2021 04:10:11
User entered 'No (N)'	System	01 Feb 2021 04:10:11

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2021-01-31T23:09:54', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '6d2f4162-83dd-44e8-808b-7c0b4ced1d5e'	System	01 Feb 2021 04:10:11
User entered 'No (N)'	System	01 Feb 2021 04:10:11

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-01-31T23:10:07', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '6d2f4162-83dd-44e8-808b-7c0b4ced1d5e'	System	01 Feb 2021 04:10:11
User entered '31 Jan 2021 23:10:07'	System	01 Feb 2021 04:10:11

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2021-02-07T12:17:08', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '05ab5b78-fda7-4079-87c3-225a8b6fab23'	System	07 Feb 2021 17:17:23
User entered 'No (N)'	System	07 Feb 2021 17:17:23

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2021-02-07T12:17:15', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '05ab5b78-fda7-4079-87c3-225a8b6fab23'	System	07 Feb 2021 17:17:23
User entered 'No (N)'	System	07 Feb 2021 17:17:23

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-02-07T12:17:19', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '05ab5b78-fda7-4079-87c3-225a8b6fab23'	System	07 Feb 2021 17:17:23
User entered '07 Feb 2021 12:17:19'	System	07 Feb 2021 17:17:23

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2021-02-14T09:25:10', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'ab2ac5fc-86c4-45de-8547-29d3e6cfd492'	System	14 Feb 2021 14:25:16
User entered 'No (N)'	System	14 Feb 2021 14:25:16

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2021-02-14T09:25:03', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'ab2ac5fc-86c4-45de-8547-29d3e6cfd492'	System	14 Feb 2021 14:25:16
User entered 'No (N)'	System	14 Feb 2021 14:25:16

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-02-14T09:25:13', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'ab2ac5fc-86c4-45de-8547-29d3e6cfd492'	System	14 Feb 2021 14:25:16
User entered '14 Feb 2021 09:25:13'	System	14 Feb 2021 14:25:16

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2021-02-21T00:05:08', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8b10c6eb-c4ae-4cef-9c34-f99bc8d0edc8'	System	21 Feb 2021 05:05:29
User entered 'No (N)'	System	21 Feb 2021 05:05:29

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2021-02-21T00:05:15', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8b10c6eb-c4ae-4cef-9c34-f99bc8d0edc8'	System	21 Feb 2021 05:05:29
User entered 'No (N)'	System	21 Feb 2021 05:05:29

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-02-21T00:05:25', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '8b10c6eb-c4ae-4cef-9c34-f99bc8d0edc8'	System	21 Feb 2021 05:05:29
User entered '21 Feb 2021 00:05:25'	System	21 Feb 2021 05:05:29

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2021-03-01T08:40:07-05:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'a2abacc2-b34e-46ec-8795-dfb18f8abef9' User entered 'No (N)'	System	01 Mar 2021 13:40:22
	System	01 Mar 2021 13:40:22

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2021-03-01T08:40:16-05:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'a2abacc2-b34e-46ec-8795-dfb18f8abef9'	System	01 Mar 2021 13:40:22
User entered 'No (N)'	System	01 Mar 2021 13:40:22

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-03-01T08:40:20-05:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'a2abacc2-b34e-46ec-8795-dfb18f8abef9' User entered '01 Mar 2021 08:40:20'	System	01 Mar 2021 13:40:22
	System	01 Mar 2021 13:40:22

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2021-03-07T00:04:25-05:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '4b34f871-b3e0-4400-b2c9-c90ff4480943'	System	07 Mar 2021 05:05:56
User entered 'No (N)'	System	07 Mar 2021 05:05:56

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2021-03-07T00:04:32-05:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '4b34f871-b3e0-4400-b2c9-c90ff4480943'	System	07 Mar 2021 05:05:56
User entered 'No (N)'	System	07 Mar 2021 05:05:56

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-03-07T00:04:37-05:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '4b34f871-b3e0-4400-b2c9-c90ff4480943' User entered '07 Mar 2021 00:04:37'	System	07 Mar 2021 05:05:56
	System	07 Mar 2021 05:05:56

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2021-03-14T00:03:03-05:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'ab7c35ac-2a39-4e51-89b3-04f809c862fd'	System	14 Mar 2021 05:07:27
User entered 'No (N)'	System	14 Mar 2021 05:07:27

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2021-03-14T00:03:09-05:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'ab7c35ac-2a39-4e51-89b3-04f809c862fd'	System	14 Mar 2021 05:07:27
User entered 'No (N)'	System	14 Mar 2021 05:07:27

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-03-14T00:03:13-05:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'ab7c35ac-2a39-4e51-89b3-04f809c862fd' User entered '14 Mar 2021 00:03:13'	System	14 Mar 2021 05:07:27
	System	14 Mar 2021 05:07:27

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2021-03-23T00:29:08-04:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '0d469c1a-9b1b-4ed8-a665-51b254be2e61'	System	23 Mar 2021 04:29:23
User entered 'No (N)'	System	23 Mar 2021 04:29:23

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2021-03-23T00:29:14-04:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '0d469c1a-9b1b-4ed8-a665-51b254be2e61'	System	23 Mar 2021 04:29:23
User entered 'No (N)'	System	23 Mar 2021 04:29:23

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-03-23T00:29:17-04:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '0d469c1a-9b1b-4ed8-a665-51b254be2e61'	System	23 Mar 2021 04:29:23
User entered '23 Mar 2021 00:29:17'	System	23 Mar 2021 04:29:23

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2021-03-28T00:11:41-04:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '79e57875-f23b-4e19-8665-9d07e360aa92'	System	28 Mar 2021 04:12:01
User entered 'No (N)'	System	28 Mar 2021 04:12:01

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2021-03-28T00:11:53-04:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '79e57875-f23b-4e19-8665-9d07e360aa92'	System	28 Mar 2021 04:12:01
User entered 'No (N)'	System	28 Mar 2021 04:12:01

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-03-28T00:11:57-04:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '79e57875-f23b-4e19-8665-9d07e360aa92' User entered '28 Mar 2021 00:11:57'	System	28 Mar 2021 04:12:01
	System	28 Mar 2021 04:12:01

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2021-04-04T09:40:16-04:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c475e8d5-24bc-4840-b565-28fbb5fb971e' User entered 'No (N)'	System	04 Apr 2021 13:40:30
	System	04 Apr 2021 13:40:30

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2021-04-04T09:40:23-04:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c475e8d5-24bc-4840-b565-28fbb5fb971e'	System	04 Apr 2021 13:40:30
User entered 'No (N)'	System	04 Apr 2021 13:40:30

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-04-04T09:40:27-04:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'c475e8d5-24bc-4840-b565-28fbb5fb971e'	System	04 Apr 2021 13:40:30
User entered '04 Apr 2021 09:40:27'	System	04 Apr 2021 13:40:30

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2021-04-12T09:17:37-04:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '804fe9b0-780d-47ab-893e-f2421f1057f2'	System	12 Apr 2021 13:17:49
User entered 'No (N)'	System	12 Apr 2021 13:17:49

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2021-04-12T09:17:43-04:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '804fe9b0-780d-47ab-893e-f2421f1057f2'	System	12 Apr 2021 13:17:49
User entered 'No (N)'	System	12 Apr 2021 13:17:49

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-04-12T09:17:46-04:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '804fe9b0-780d-47ab-893e-f2421f1057f2'	System	12 Apr 2021 13:17:49
User entered '12 Apr 2021 09:17:46'	System	12 Apr 2021 13:17:49

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2021-04-18T08:23:45-04:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'dac81c5a-88f9-477b-96ae-7c6df6b3e3a1'	System	18 Apr 2021 12:24:02
User entered 'No (N)'	System	18 Apr 2021 12:24:02

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2021-04-18T08:23:55-04:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'dac81c5a-88f9-477b-96ae-7c6df6b3e3a1'	System	18 Apr 2021 12:24:02
User entered 'No (N)'	System	18 Apr 2021 12:24:02

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-04-18T08:23:59-04:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'dac81c5a-88f9-477b-96ae-7c6df6b3e3a1'	System	18 Apr 2021 12:24:02
User entered '18 Apr 2021 08:23:59'	System	18 Apr 2021 12:24:02

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2021-04-25T00:21:43-04:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'fe85d667-e4b6-48e9-9527-b54f8803c18d'	System	25 Apr 2021 04:21:59
User entered 'No (N)'	System	25 Apr 2021 04:21:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2021-04-25T00:21:50-04:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'fe85d667-e4b6-48e9-9527-b54f8803c18d'	System	25 Apr 2021 04:21:59
User entered 'No (N)'	System	25 Apr 2021 04:21:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-04-25T00:21:56-04:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: 'fe85d667-e4b6-48e9-9527-b54f8803c18d'	System	25 Apr 2021 04:21:59
User entered '25 Apr 2021 00:21:56'	System	25 Apr 2021 04:21:59

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[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 (60a92855f87d290c)', Time: '2021-05-02T23:18:09-04:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9b8459cb-ee99-4ffe-ae4b-ea82ea06d950'	System	03 May 2021 03:18:28
User entered 'No (N)'	System	03 May 2021 03:18:28

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

Have you been exposed to someone with 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 (60a92855f87d290c)', Time: '2021-05-02T23:18:17-04:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9b8459cb-ee99-4ffe-ae4b-ea82ea06d950'	System	03 May 2021 03:18:28
User entered 'No (N)'	System	03 May 2021 03:18:28

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-05-02T23:18:20-04:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '9b8459cb-ee99-4ffe-ae4b-ea82ea06d950'	System	03 May 2021 03:18:28
User entered '02 May 2021 23:18:20'	System	03 May 2021 03:18:28

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 04:11:14

US3482240

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:48:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 04:11:14

US3482240

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:48:53

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-03-01T08:40:29-05:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '46450bc0-24a3-4bfa-939c-41dcca7f01c9'	System	01 Mar 2021 13:40:37
User entered 'No (N)'	System	01 Mar 2021 13:40:37

US3482240

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:48:53

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:20:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60a92855f87d290c)', Time: '2021-03-01T08:40:35-05:00', User OID: 'PatientReportedOutcome (US3482240)', ODM File OID: '46450bc0-24a3-4bfa-939c-41dcca7f01c9' User entered '01 Mar 2021 08:40:35'	System	01 Mar 2021 13:40:37
	System	01 Mar 2021 13:40:37

US3482240

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:28:01

US3482240

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
User entered '24 Nov 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:28:01

US3482240

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:28:01

US3482240

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:28:01

US3482240

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:27:42

US3482240

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:23
User entered 'I'	System	24 Nov 2020 17:27:42

US3482240

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:02:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 13:35:36

US3482240

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:02:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 13:35:36

US3482240

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:02:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 13:35:36

US3482240

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:02:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 13:35:36

US3482240

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:02:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 13:35:18

US3482240

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:02:16
User entered 'I'	System	29 Dec 2020 13:35:18

US3482240

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:02:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:59

US3482240

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:02:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:59

US3482240

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:02:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:59

US3482240

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:02:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:59

US3482240

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:02:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:37:06

US3482240

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:02:16
User entered 'I'	System	27 Jan 2021 21:37:06

US3482240

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:02:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:49:14

US3482240

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:02:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:49:14

US3482240

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:02:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:49:14

US3482240

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:48:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:02:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:49:14

US3482240

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:02:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:49:21

US3482240

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:02:16
User entered 'I'	System	23 Feb 2021 15:49:21

US3482240

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 19:40:23

US3482240

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
	(b) (4)	
User entered '16 Mar 2021'	(b) (4), (b) (6)	16 Mar 2021 19:40:23

US3482240

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

[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 10:28:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Mar 2021 19:40:23

US3482240

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User entered 'VISIT4'	System	16 Mar 2021 19:40:23

US3482240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
	(b) (4)	
User entered 'No (N)'	Michelle Wiles (b) (4)	31 Mar 2021 23:26:31
	(b) (4)	

US3482240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	31 Mar 2021 23:26:31
	(b) (4)	

US3482240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	31 Mar 2021 23:26:31
	(b) (4)	

US3482240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User entered empty.	System	31 Mar 2021 23:26:31

US3482240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	31 Mar 2021 23:26:31
	(b) (4)	

US3482240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	31 Mar 2021 23:26:31
	(b) (4)	

US3482240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	31 Mar 2021 23:26:31
	(b) (4)	

US3482240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	31 Mar 2021 23:26:31
	(b) (4)	

US3482240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User entered empty.	System	31 Mar 2021 23:26:31

US3482240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	31 Mar 2021 23:26:31
	(b) (4)	

US3482240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User entered empty.	System	31 Mar 2021 23:26:31

US3482240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	31 Mar 2021 23:26:31
	(b) (4)	

US3482240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User entered empty.	System	31 Mar 2021 23:26:31

US3482240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	31 Mar 2021 23:26:31
	(b) (4)	

US3482240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User entered empty.	System	31 Mar 2021 23:26:31

US3482240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26

US3482240

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:48:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26

US3482240

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:48:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 19:41:17

US3482240

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:48:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
	(b) (4)	
User entered '16 Mar 2021'	(b) (4), (b) (6)	16 Mar 2021 19:41:17

US3482240

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:48:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 19:41:44

US3482240

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:48:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
	(b) (4)	
User entered '16 Mar 2021'	(b) (4), (b) (6)	16 Mar 2021 19:41:44

US3482240

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:48:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
	(b) (4)	
User entered '15:16'	(b) (4), (b) (6)	16 Mar 2021 19:41:44

US3482240

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:48:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User entered '16 Mar 2021 15:16'	System	16 Mar 2021 19:41:44

US3482240

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:30:15
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 19:41:48

US3482240

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:48:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:28:26
User entered 'I'	System	16 Mar 2021 19:41:48

US3482240

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

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:49:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
	(b) (4)	
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	08 Jan 2021 01:46:11

US3482240

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

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:49:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
	(b) (4)	
User entered '7 Jan 2021'	Hollie Macenczak (b) (4)	08 Jan 2021 01:46:11

US3482240

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

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:49:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
	(b) (4)	
User entered 'Clinic (Clinic)'	Hollie Macenczak (b) (4)	08 Jan 2021 01:46:11

US3482240

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

Form: Visit Date

Generated On: 09 Jun 2021 17:48:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:49:24
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 01:46:11

US3482240

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

Form: Unblinding

Generated On: 09 Jun 2021 17:48:53

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:49:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
	(b) (4)	
User entered '07 Jan 2021'	Hollie Macenczak (b) (4)	08 Jan 2021 01:47:40

US3482240

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

Form: Unblinding

Generated On: 09 Jun 2021 17:48:53

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:49:24
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
User entered '0'	Mari Hart (b) (4)	09 Apr 2021 16:53:39
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:44:15

US3482240

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

Form: Unblinding

Generated On: 09 Jun 2021 17:48:53

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:49:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
	(b) (4)	
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	08 Jan 2021 01:47:40

US3482240

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

Form: Unblinding

Generated On: 09 Jun 2021 17:48:53

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:49:24
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
User closed query 'Per Sponsor Review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 10:32:22
Query 'Per Sponsor Review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	Mari Hart (b) (4) (b) (4)	09 Apr 2021 16:53:45
User entered 'Amendment 6 or later (Amendment 6 or later)'	Mari Hart (b) (4) (b) (4)	09 Apr 2021 16:53:39
User opened query 'Per Sponsor Review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 07:04:34
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:44:15

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

Form: Unblinding

Generated On: 09 Jun 2021 17:48:53

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:49:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
	(b) (4)	
User entered '07 Jan 2021'	Hollie Macenczak (b) (4)	08 Jan 2021 01:47:40

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

Form: Unblinding

Generated On: 09 Jun 2021 17:48:53

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:49:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Hollie Macenczak (b) (4)	08 Jan 2021 01:47:40

US3482240

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

Form: Unblinding

Generated On: 09 Jun 2021 17:48:53

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:49:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
	(b) (4)	
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 09:07:21
User entered 'mRNA-1273 (mRNA-1273)'	Hollie Macenczak (b) (4)	08 Jan 2021 01:47:40

US3482240

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

Form: Unblinding

Generated On: 09 Jun 2021 17:48:53

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:49:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
	(b) (4)	
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 09:07:21
User entered 'mRNA-1273 (mRNA-1273)'	Hollie Macenczak (b) (4)	08 Jan 2021 01:47:40

US3482240

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

Form: Unblinding

Generated On: 09 Jun 2021 17:48:53

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:49:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
	(b) (4)	
User entered 'No (N)'	Hollie Macenczak (b) (4)	08 Jan 2021 01:47:40

US3482240

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

Form: Unblinding

Generated On: 09 Jun 2021 17:48:53

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:49:24
User entered empty.	System	08 Jan 2021 01:47:40

US3482240

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

Form: Unblinding

Generated On: 09 Jun 2021 17:48:53

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:49:24
User entered empty.	System	08 Jan 2021 01:47:40

US3482240

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:48:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:49:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
	(b) (4)	
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	08 Jan 2021 01:48:05

US3482240

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:48:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:49:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
	(b) (4)	
User entered '7 Jan 2021'	Hollie Macenczak (b) (4)	08 Jan 2021 01:48:05

US3482240

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:48:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:49:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
	(b) (4)	
User entered '15:10'	Hollie Macenczak (b) (4)	08 Jan 2021 01:48:05

US3482240

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:48:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:49:24
User entered '7 Jan 2021 15:10'	System	08 Jan 2021 01:48:05

US3482240

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:48:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:49:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
	(b) (4)	
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	08 Jan 2021 01:48:22

US3482240

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:48:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:49:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
	(b) (4)	
User entered '7 Jan 2021'	Hollie Macenczak (b) (4)	08 Jan 2021 01:48:22

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:48:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:49:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:29:54
	(b) (4)	
User entered '15:13'	Hollie Macenczak (b) (4)	08 Jan 2021 01:48:22

US3482240

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:48:53

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:49:24
User entered '7 Jan 2021 15:13'	System	08 Jan 2021 01:48:22

US3482240

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:48:53

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:54:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:23:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:51:18
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	19 Jan 2021 18:20:35

US3482240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:48:53

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:48:59
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:18:47
User entered		
'USA-US106-2021-mRNA-1273-P301000005'	System	20 Jan 2021 21:18:42
User entered 'New'	(b) (4), (b) (6)	20 Jan 2021 21:18:42

US3482240

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:48:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:49:01
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Pain in extremity, LLT: Painful L arm - version MedDRA\\23.0.	Coder Import (b) (4)	19 Jan 2021 18:25:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Jan 2021 18:25:09
Data point term sent to Coder	System	19 Jan 2021 18:24:25
User entered 'Left arm Pain'	Joy Winters (b) (4)	19 Jan 2021 18:24:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:48:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:49:02
User entered 'Yes (Y)'	Joy Winters (b) (4)	19 Jan 2021 18:24:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:48:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:49:04
User entered 'No (N)'	Joy Winters (b) (4)	19 Jan 2021 18:24:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:48:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:49:06
User entered 'No (N)'	Joy Winters (b) (4)	19 Jan 2021 18:24:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:48:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User closed query 'PV Query: Please confirm the event onset date for AE: left arm pain as it was reported the subject lifted some heavy items that were delivered on 11 Jan 2021 and it was suspected the arm pain was caused by lifting heavy objects.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:01:05
Query 'PV Query: Please confirm the event onset date for AE: left arm pain as it was reported the subject lifted some heavy items that were delivered on 11 Jan 2021 and it was suspected the arm pain was caused by lifting heavy objects.' answered with 'subject seen in clinic on 01/07/21 for OL visit. subject stated arm pain started on 1/07/21 as a result of phlebotomy technique. site provider discussed episode with subject, and subject insists pain started on 01/07/21. arm pain progressed and subject eventually went to the emergency room, and later admitted. while admitted subject was found to have sepsis due to left hand cellulitis 2/2 cat/bite/scratch. during the course of hospitalization subject noted he had items delivered on 1/11/21 which contributed to arm pain. ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:18:19
User opened query 'PV Query: Please confirm the event onset date for AE: left arm pain as it was reported the subject lifted some heavy items that were delivered on 11 Jan 2021 and it was suspected the arm pain was caused by lifting heavy objects.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 19:05:00
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:49:09
User entered '07 Jan 2021'	Joy Winters (b) (4) (b) (4)	19 Jan 2021 18:24:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:48:53

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:49:11
User entered empty.	Joy Winters (b) (4)	19 Jan 2021 18:24:22
	(b) (4)	

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Folder: Adverse Events

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Jan 2021 18:24:22

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 20:04:13
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	16 Mar 2021 20:04:13
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:49:13
User entered 'Yes (Y)'	Joy Winters (b) (4)	19 Jan 2021 18:24:22
	(b) (4)	

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Folder: Adverse Events

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User closed query ' PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:14:37
Query ' PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 20:04:20
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 20:04:13
User entered '15 Feb 2021' reason for change: New Information	(b) (4), (b) (6)	16 Mar 2021 20:04:13
User opened query ' PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 19:04:36
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:49:14
User entered empty.	Joy Winters (b) (4) (b) (4)	19 Jan 2021 18:24:22

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:49:16
User entered empty.	Joy Winters (b) (4) (b) (4)	19 Jan 2021 18:24:22

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Folder: Adverse Events

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Jan 2021 18:24:22

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:49:45
User entered 'Grade 3/Severe (Grade 3/Severe)'	Joy Winters (b) (4)	19 Jan 2021 18:24:22
	(b) (4)	

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:49:53
User entered 'Yes (Y)'	Joy Winters (b) (4)	19 Jan 2021 18:24:22
	(b) (4)	

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Folder: Adverse Events

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:49:55
User entered '0'	Joy Winters (b) (4)	19 Jan 2021 18:24:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:49:56
User entered '0'	Joy Winters (b) (4)	19 Jan 2021 18:24:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:48:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:50:04
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	20 Jan 2021 21:27:36
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject was admitted to the hospital 19Jan2021 and is not in ICU but is in inpatient unit.	Joy Winters (b) (4)	19 Jan 2021 18:26:22
JCW 19JAN2021' (Site from System).	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	19 Jan 2021 18:24:22
User entered 'I'	Joy Winters (b) (4)	19 Jan 2021 18:24:22
	(b) (4)	

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:50:07
User entered '19 Jan 2021'	Joy Winters (b) (4)	19 Jan 2021 18:24:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:48:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User closed query 'PV Query: Please submit the discharge summary when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:01:13
User closed query ' PV Query: Please provide the hospital discharge date when available' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 22:01:10
Query 'PV Query: Please submit the discharge summary when available.' answered with 'discharge summary submitted' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:25:22
Query ' PV Query: Please provide the hospital discharge date when available' answered with 'discharge summary submitted' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:25:14
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 20:24:46
User entered '23 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 20:24:46
User opened query 'PV Query: Please submit the discharge summary when available.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 19:05:55
User opened query ' PV Query: Please provide the hospital discharge date when available' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 19:03:41
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:50:10
User entered empty.	Joy Winters (b) (4) (b) (4)	19 Jan 2021 18:24:22

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:50:11
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	19 Jan 2021 18:24:22

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:50:13
User entered empty.	Joy Winters (b) (4)	19 Jan 2021 18:24:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:50:15
User entered '0'	Joy Winters (b) (4)	19 Jan 2021 18:24:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:50:16
User entered '0'	Joy Winters (b) (4)	19 Jan 2021 18:24:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:50:18
User entered '0'	Joy Winters (b) (4)	19 Jan 2021 18:24:22
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:50:20
User entered 'Not Related (NOT RELATED)'	Joy Winters (b) (4)	19 Jan 2021 18:24:22
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:50:22
User entered 'Related (RELATED)'	Joy Winters (b) (4)	19 Jan 2021 18:24:22
	(b) (4)	

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:50:24
User entered 'Not Applicable (NOT APPLICABLE)'	Joy Winters (b) (4) (b) (4)	19 Jan 2021 18:24:22

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
Signature has been broken.	(b) (4)	
	Mari Hart (b) (4)	09 Apr 2021 18:30:26
	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:50:25
User entered '0'	Joy Winters (b) (4)	19 Jan 2021 18:24:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
Signature has been broken.	(b) (4)	
	Mari Hart (b) (4)	09 Apr 2021 18:33:45
	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 07:40:18
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'concom med added' (Site from DM).	Mari Hart (b) (4)	23 Mar 2021 18:57:47
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 02:12:02
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 22:01:45
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 'hospital records submitted' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:27:55

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Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
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)	29 Jan 2021 19:04:02
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:50:27
User entered 'I'	Joy Winters (b) (4)	19 Jan 2021 18:24:22
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:50:28
User entered '0'	Joy Winters (b) (4)	19 Jan 2021 18:24:22
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:14:44
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 20:04:26
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 20:04:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	16 Mar 2021 20:04:13
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 19:04:09
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:50:30
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Joy Winters (b) (4) (b) (4)	19 Jan 2021 18:24:22

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:50:32
User entered empty.	Joy Winters (b) (4) (b) (4)	19 Jan 2021 18:24:22

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User closed query 'PV Query: Please confirm if cellulitis and hyponatremia meets criteria for separate AE/SAE reporting. If yes, please add applicable events to the EDC.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:48:06
User closed query 'Per CDM re-query: Narrative = BLOOD CULTURE POSITIVE FOR PASTEURELLA. Please review and add the procedure/test in con proc eCRF as appropriate else clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 15:14:15
Query 'Per CDM re-query: Narrative = BLOOD CULTURE POSITIVE FOR PASTEURELLA. Please review and add the procedure/test in con proc eCRF as appropriate else clarify. ' answered with 'Will add con proc' (Site from DM).	Mari Hart (b) (4) (b) (4)	25 Mar 2021 23:01:52
Query 'PV Query: Please confirm if cellulitis and hyponatremia meets criteria for separate AE/SAE reporting. If yes, please add applicable events to the EDC.' answered with 'Part of hospitalization. Not separate SAE' (Site from Safety).	Mari Hart (b) (4) (b) (4)	25 Mar 2021 23:01:29
User opened query 'PV Query: Please confirm if cellulitis and hyponatremia meets criteria for separate AE/SAE reporting. If yes, please add applicable events to the EDC.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 20:01:26
User closed query 'PV Query: Please confirm if cellulitis and hyponatremia meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 20:01:26
User closed query 'Per DM CLR: Narrative = BLOOD CULTURE POSITIVE FOR PASTEURELLA. 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)	24 Mar 2021 07:45:28
User opened query 'Per CDM re-query: Narrative = BLOOD CULTURE POSITIVE FOR PASTEURELLA. Please review and add the procedure/test in con proc eCRF as appropriate else clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 07:45:26

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = ERYTHEMA OVER AC AREA AND TENDERNESS AND INDENTATION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 07:43:43
Query 'Per DM CLR: Narrative = ERYTHEMA OVER AC AREA AND TENDERNESS AND INDENTATION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'symptoms related to SAE ' (Site from DM).	Mari Hart (b) (4) (b) (4)	23 Mar 2021 19:02:59
Query 'Per DM CLR: Narrative = BLOOD CULTURE POSITIVE FOR PASTEURELLA. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'reported with SAE and hospitalization' (Site from DM).	Mari Hart (b) (4) (b) (4)	23 Mar 2021 19:01:40
Query 'PV Query: Please confirm if cellulitis and hyponatremia meets criteria for separate AE/SAE reporting.' answered with 'SAE reported with hospitalization' (Site from Safety).	Mari Hart (b) (4) (b) (4)	23 Mar 2021 19:00:58
User opened query 'Per DM CLR: Narrative = BLOOD CULTURE POSITIVE FOR PASTEURELLA. 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)	23 Feb 2021 02:11:52
User opened query 'Per DM CLR: Narrative = ERYTHEMA OVER AC AREA AND TENDERNESS AND INDENTATION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 02:11:47
User opened query 'PV Query: Please confirm if cellulitis and hyponatremia meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 19:03:21
DataPoint Un-verified.	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:22:06

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'ERYTHEMA OVER AC AREA AND TENDERNESS AND INDENTATION. HOWEVER LIKELY DUE TO CAT SCRATCH OR BITE. ADMITTED FOR CELLULITIS AND HYPONATREMIA. BLOOD CULTURE POSITIVE FOR PASTEURELLA' reason for change: Data Entry Error	Joy Winters (b) (4)	22 Jan 2021 18:22:06
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:51:09
User entered 'ERYTHEMA OVER AC AREA AND TENDERNESS AND INDENTATION. HOWEVER LIKELY DUE TO CAT SCRATCH OR BITE. ADMITTED FOR CELLULITIS AND HYPONATREMIA.' reason for change: Data Entry Error	Joy Winters (b) (4)	19 Jan 2021 21:45:57
User entered 'Erythema over AC area and tenderness and indentation. Admitted for possible cellulitis and hypokalemia.'	Joy Winters (b) (4)	19 Jan 2021 18:24:22

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Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Jan 2021 18:24:22

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Jan 2021 18:24:22

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Jan 2021 18:24:22

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 20:54:25
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 15:33:11
User entered	(b) (4), (b) (6)	25 Jan 2021 15:33:01
'USA-US106-2021-mRNA-1273-P301000005'		

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:54:29
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute kidney injury - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 18:25:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 18:25:04
Data point term sent to Coder	System	22 Jan 2021 18:24:29
User entered 'ACUTE KIDNEY INJURY'	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:24:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:54:31
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:24:01

US3482240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:54:41
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:24:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 20:54:43
User entered 'No (N)'	Joy Winters (b) (4)	22 Jan 2021 18:24:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:54:47
User entered '19 Jan 2021' reason for change: Data Entry Error	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:37:27
User entered '20 Jan 2021'	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:24:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 20:54:49
User entered empty.	Joy Winters (b) (4)	22 Jan 2021 18:24:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 18:24:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 20:00:40
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	16 Mar 2021 20:00:40
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:54:52
User entered 'Yes (Y)'	Joy Winters (b) (4)	22 Jan 2021 18:24:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:14:58
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 20:00:59
User entered '23 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	16 Mar 2021 20:00:40
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 19:08:11
User entered empty.	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:24:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:55:03
User entered empty.	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:24:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 18:24:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:55:06
User entered 'Grade 3/Severe (Grade 3/Severe)'	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:24:01

US3482240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:55:09
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:24:01

US3482240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 20:55:11
User entered '0'	Joy Winters (b) (4)	22 Jan 2021 18:24:01
	(b) (4)	

US3482240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:55:31
User entered '0'	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:24:01

US3482240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:55:35
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	25 Jan 2021 16:39:10
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Hospital admission date 19JAN2021' (Site from System).	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:38:23
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	22 Jan 2021 18:24:01
User entered 'I'	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:24:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 20:56:04
User entered '19 Jan 2021'	Joy Winters (b) (4)	22 Jan 2021 18:24:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User closed query 'PV Query: Please submit the discharge summary when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:02:25
User closed query 'PV Query: Please provide the hospital discharge date when available' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 22:02:22
Query 'PV Query: Please submit the discharge summary when available.' answered with 'discharge summary submitted' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:28:39
Query 'PV Query: Please provide the hospital discharge date when available' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 19:55:34
User entered '23 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 19:55:15
User opened query 'PV Query: Please submit the discharge summary when available.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 19:08:30
User opened query 'PV Query: Please provide the hospital discharge date when available' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 19:06:59
User entered empty.	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:24:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:09:22
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:24:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 21:09:24
User entered empty.	Joy Winters (b) (4)	22 Jan 2021 18:24:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 21:09:28
User entered '0'	Joy Winters (b) (4)	22 Jan 2021 18:24:01
	(b) (4)	

US3482240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:09:31
User entered '0'	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:24:01

US3482240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 21:09:35
User entered '0'	Joy Winters (b) (4)	22 Jan 2021 18:24:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:09:38
User entered 'Not Related (NOT RELATED)'	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:24:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 21:09:43
User entered 'Not Related (NOT RELATED)'	Joy Winters (b) (4)	22 Jan 2021 18:24:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:09:45
User entered 'Not Applicable (NOT APPLICABLE)'	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:24:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

None

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 21:10:00
User entered '0'	Joy Winters (b) (4)	22 Jan 2021 18:24:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 07:47:08
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updating con meds' (Site from DM).	Mari Hart (b) (4) (b) (4)	23 Mar 2021 19:06:28
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 02:16:09
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 22:02:31
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 'hospital records submitted' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:28:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
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)	29 Jan 2021 19:07:16
User entered 'I'	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:24:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 21:10:55
User entered '0'	Joy Winters (b) (4)	22 Jan 2021 18:24:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User closed query ' PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:15:02
Query ' PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 20:01:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	16 Mar 2021 20:00:40
User opened query ' PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 19:07:44
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:24:01

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Form: Adverse Events (2)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:12:04
User entered empty.	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:24:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per CDM RQ: Response of 'Bacteremia will be added as AE' is noted. However, there is no AE for Bacteremia present. Please review and update, else clarify. Thank you!' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 13:39:14
Query 'Per CDM RQ: Response of 'Bacteremia will be added as AE' is noted. However, there is no AE for Bacteremia present. Please review and update, else clarify. Thank you!' answered with 'Bacteremia was reason for hospitalization and is captured as SAE.' (Site from DM).	Mari Hart (b) (4) (b) (4)	14 Apr 2021 19:51:30
User opened query 'Per CDM RQ: Response of 'Bacteremia will be added as AE' is noted. However, there is no AE for Bacteremia present. Please review and update, else clarify. Thank you!' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 18:59:56
User closed query 'Per DM CLR - RQ: Site's response noted. However, it was not clarified if BACTERIMIA should be recorded as a separate AE. Review and ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 18:57:37
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	12 Apr 2021 16:18:18
Query 'Per DM CLR - RQ: Site's response noted. However, it was not clarified if BACTERIMIA should be recorded as a separate AE. Review and ensure to record this medical condition in the AE eCRF as appropriate. ' answered with 'Bacteremia will be added as AE' (Site from DM).	Mari Hart (b) (4) (b) (4)	09 Apr 2021 18:27:05
Signature has been broken.	Mari Hart (b) (4) (b) (4)	09 Apr 2021 18:26:18
User entered 'ACUTE KIDNEY INJURY' reason for change: Per Query Resolution	Mari Hart (b) (4) (b) (4)	09 Apr 2021 18:26:18
User opened query 'Per DM CLR - RQ: Site's response noted. However, it was not clarified if BACTERIMIA should be recorded as a separate AE. Review and ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 12:59:52
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	26 Mar 2021 22:31:21

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = HAS BACTERIMIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 13:07:20
User closed query 'Per DM CLR: Narrative = RECEIVING IVF. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 07:47:20
Query 'Per DM CLR: Narrative = RECEIVING IVF. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'adding to con com meds per hospitalization records' (Site from DM).	Mari Hart (b) (4) (b) (4)	23 Mar 2021 19:10:11
Query 'Per DM CLR: Narrative = HAS BACTERIMIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'SAE' (Site from DM).	Mari Hart (b) (4) (b) (4)	23 Mar 2021 19:09:40
User opened query 'Per DM CLR: Narrative = RECEIVING IVF. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 02:16:03
User opened query 'Per DM CLR: Narrative = HAS BACTERIMIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 02:15:58
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Jan 2021 18:37:27
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	22 Jan 2021 18:37:27
User entered 'Has bacterimia and acute kidney injury; receiving IVF' reason for change: Data Entry Error	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:37:27

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Jan 2021 18:24:01
User entered empty.	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:24:01

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Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Jan 2021 18:24:01

US3482240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Jan 2021 18:24:01

US3482240

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:48:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Jan 2021 18:24:01

US3482240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal pain, LLT: Shoulder pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	22 Jan 2021 18:28:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 18:28:05
Data point term sent to Coder	System	22 Jan 2021 18:27:30
User entered 'LEFT SHOULDER PAIN'	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Yes (Y)'	Joy Winters (b) (4)	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	Joy Winters (b) (4)	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	Joy Winters (b) (4)	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '11 Jan 2021'	(b) (4) Joy Winters (b) (4)	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	Joy Winters (b) (4)	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User entered empty.	System	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	
User entered 'No (N)' reason for change: New Information	System	18 Mar 2021 16:03:25
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	18 Mar 2021 16:03:25
User entered 'Yes (Y)'	System	16 Mar 2021 20:04:57
	Joy Winters (b) (4)	22 Jan 2021 18:26:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 07:19:50
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	18 Mar 2021 16:03:53
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	16 Mar 2021 20:04:57
User entered '15 Feb 2021' reason for change: New Information	(b) (4), (b) (6)	16 Mar 2021 20:04:57
User entered empty.	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	Joy Winters (b) (4)	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User entered empty.	System	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Grade 2/Moderate (Grade 2/Moderate)	(b) (4)	
reason for change: Data Entry Error	Joy Winters (b) (4)	22 Jan 2021 18:35:37
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4)	
	Joy Winters (b) (4)	22 Jan 2021 18:26:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Joy Winters (b) (4)	22 Jan 2021 18:35:37
User entered 'Yes (Y)'	(b) (4)	
	Joy Winters (b) (4)	22 Jan 2021 18:26:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	Joy Winters (b) (4)	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	Joy Winters (b) (4)	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4)	22 Jan 2021 18:35:37
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		22 Jan 2021 18:35:37
User entered '0' reason for change: Data Entry Error	Joy Winters (b) (4)	22 Jan 2021 18:35:37
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4)	22 Jan 2021 18:26:32
User entered '1'	Joy Winters (b) (4)	22 Jan 2021 18:26:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty; reason for change Data Entry Error	(b) (4)	
	Joy Winters (b) (4)	22 Jan 2021 18:35:37
User entered '19 Jan 2021'	(b) (4)	
	Joy Winters (b) (4)	22 Jan 2021 18:26:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	Joy Winters (b) (4)	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty; reason for change Data Entry Error	(b) (4)	
	Joy Winters (b) (4)	22 Jan 2021 18:35:37
User entered 'No (N)'	(b) (4)	
	Joy Winters (b) (4)	22 Jan 2021 18:26:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	Joy Winters (b) (4)	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	Joy Winters (b) (4)	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	Joy Winters (b) (4)	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	Joy Winters (b) (4)	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Not Related (NOT RELATED)'	Joy Winters (b) (4)	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Not Related (NOT RELATED)'	Joy Winters (b) (4)	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Not Applicable (NOT APPLICABLE)'	Joy Winters (b) (4)	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	Joy Winters (b) (4)	22 Jan 2021 18:26:32

US3482240

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 07:48:58
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'com meds updated' (Site from DM).	Mari Hart (b) (4) (b) (4)	23 Mar 2021 19:04:24
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 02:16:29
User entered 'I'	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	Joy Winters (b) (4)	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User closed query 'Per CDM: Outcome is Not recovered / Not resolved; However end date is provided. Please update the outcome as appropriate else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 07:49:03
Query 'Per CDM: Outcome is Not recovered / Not resolved; However end date is provided. Please update the outcome as appropriate else clarify. ' answered with 'Updated per query ' (Site from DM).	Joy Winters (b) (4) (b) (4)	23 Mar 2021 18:44:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Joy Winters (b) (4) (b) (4)	23 Mar 2021 18:44:15
User opened query 'Per CDM: Outcome is Not recovered / Not resolved; However end date is provided. Please update the outcome as appropriate else clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 07:20:54
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	Joy Winters (b) (4)	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User closed query 'Per DM CLR: Narrative = MRI. 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) (4), (b) (6)	24 Mar 2021 07:49:36
Query 'Per DM CLR: Narrative = MRI. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'ConProc ECRF was completed today for query resolution JCW 23MAR2021' (Site from DM).	Joy Winters (b) (4) (b) (4)	23 Mar 2021 19:04:36
User opened query 'Per DM CLR: Narrative = MRI. 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)	23 Feb 2021 02:16:23
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Jan 2021 18:35:37
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	22 Jan 2021 18:35:37
User entered 'Suspected rotator cuff injury from lifting heavy objects on 01/11/2021. MRI is absent of septic arthritis.' reason for change: Data Entry Error	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:35:37
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Jan 2021 18:26:32
User entered empty.	Joy Winters (b) (4) (b) (4)	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User entered '0'	System	22 Jan 2021 18:35:37
User entered '1'	System	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User entered 'I'	System	22 Jan 2021 18:26:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:48:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:15
User entered '0'	System	22 Jan 2021 18:26:32

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:48:53

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:54:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:53:59
User entered 'Yes (Y)'	Michele McCullough (b) (4)	18 Sep 2020 18:12:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:48:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STERIODS, PRODUCT: GLUCOSAMINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Sep 2020 22:57:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 22:57:44
Data point term sent to Coder	System	18 Sep 2020 18:14:42
User entered 'glucosamine'	Michele McCullough (b) (4)	18 Sep 2020 18:14:40

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:48:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User closed query 'Missed - Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis, refer to CCGs. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 06:17:12
Query 'Missed - Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis, refer to CCGs. Update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 15:40:08
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 15:40:01
User opened query 'Missed - Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis, refer to CCGs. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:57:18
User entered 'No (N)'	Michele McCullough (b) (4)	18 Sep 2020 18:14:40

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:48:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'health promotion'	Michele McCullough (b) (4)	18 Sep 2020 18:14:40

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:48:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
Signature has been broken.	(b) (4)	
	Lauren Hewitt (b) (4)	08 Apr 2021 17:43:19
	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 11:21:12
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	Michele McCullough (b) (4)	02 Dec 2020 15:04:44
User entered '1500' reason for change: Per Query Resolution	Michele McCullough (b) (4)	02 Dec 2020 15:04:39
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:31:09
User entered 'I'	Michele McCullough (b) (4)	18 Sep 2020 18:14:40

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:48:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'mg (mg)' reason for change: Per Query Resolution	Michele McCullough (b) (4)	02 Dec 2020 15:04:39
User entered 'tablet (TABLET)'	Michele McCullough (b) (4)	18 Sep 2020 18:14:40

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:48:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 18:14:40

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:48:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'twice daily (BID)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 18:14:40

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:48:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 18:14:40

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:48:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Oral (ORAL)'	Michele McCullough (b) (4)	18 Sep 2020 18:14:40

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:48:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 18:14:40

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'un UNK 2010'	Michele McCullough (b) (4)	18 Sep 2020 18:14:40

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:48:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 18:14:40

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:48:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 18:14:40

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:48:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 18:14:40

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:48:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 18:14:40

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:48:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Sep 2020 18:14:40

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 18:14:40

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 18:14:40

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:48:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Sep 2020 19:26:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:26:42
Data point term sent to Coder	System	18 Sep 2020 19:25:17
User entered 'famotidine'	Michele McCullough (b) (4)	18 Sep 2020 19:24:20

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:48:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:24:20

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:48:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'GERD'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:24:20

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:48:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '20'	Michele McCullough (b) (4)	18 Sep 2020 19:24:20

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:48:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'mg (mg)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:24:20

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:48:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:24:20

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:48:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'twice daily (BID)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:24:20

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:48:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:24:20

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:48:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Oral (ORAL)'	Michele McCullough (b) (4)	18 Sep 2020 19:24:20

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:48:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:24:20

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'un Feb 2020'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:24:20

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:48:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:24:20

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:48:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Yes (Y)'	Michele McCullough (b) (4)	18 Sep 2020 19:24:20

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:48:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:24:20

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:48:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:24:20

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:48:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Sep 2020 19:24:20

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:24:20

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 19:24:20

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:48:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Sep 2020 19:26:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:26:41
Data point term sent to Coder	System	18 Sep 2020 19:25:17
User entered 'losartan'	Michele McCullough (b) (4)	18 Sep 2020 19:25:00

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:48:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:25:00

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:48:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'hypertension'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:25:00

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:48:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '100' reason for change: Data Entry Error	(b) (4) Michele McCullough	18 Sep 2020 19:35:01
User entered '25'	(b) (4) Michele McCullough	18 Sep 2020 19:25:00
	(b) (4)	

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:48:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'mg (mg)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:25:00

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:48:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:25:00

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:48:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'once daily (QD)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:25:00

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:48:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:25:00

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:48:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Oral (ORAL)'	Michele McCullough (b) (4)	18 Sep 2020 19:25:00

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:48:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:25:00

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'un UNK 2015'	Michele McCullough (b) (4)	18 Sep 2020 19:25:00

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:48:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:25:00

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:48:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Yes (Y)'	Michele McCullough (b) (4)	18 Sep 2020 19:25:00

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:48:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:25:00

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:48:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:25:00

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:48:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:25:00

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:25:00

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 19:25:00

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:48:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Sep 2020 19:27:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:27:44
Data point term sent to Coder	System	18 Sep 2020 19:26:19
User entered 'humalog'	Michele McCullough (b) (4)	18 Sep 2020 19:25:44

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:48:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:25:44

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:48:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'diabetes'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:25:44

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:48:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '14'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:25:44

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:48:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Other (OTHER)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:25:44

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:48:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'units'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:25:44

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:48:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'twice daily (BID)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:25:44

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:48:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:25:44

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:48:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:25:44

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:48:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:25:44

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:48:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'un UNK 2000'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:25:44

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:48:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:25:44

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:48:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Yes (Y)'	Michele McCullough (b) (4)	18 Sep 2020 19:25:44

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:48:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:25:44

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:48:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:25:44

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:48:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Sep 2020 19:25:44

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:25:44

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 19:25:44

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:48:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Sep 2020 19:27:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:27:45
Data point term sent to Coder	System	18 Sep 2020 19:27:21
User entered 'lantus'	Michele McCullough (b) (4)	18 Sep 2020 19:26:26

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:48:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:26:26

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:48:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'diabetes'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:26:26

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:48:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '38'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:26:26

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:48:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Other (OTHER)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:26:26

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:48:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'units'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:26:26

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:48:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'once daily (QD)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:26:26

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:48:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:26:26

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:48:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:26:26

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:48:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:26:26

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'un UNK 2000'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:26:26

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:48:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:26:26

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:48:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:26:26

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:48:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:26:26

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:48:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:26:26

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:48:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:26:26

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:26:26

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 19:26:26

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:48:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: MUPIROCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Sep 2020 23:20:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:20:39
Data point term sent to Coder	System	18 Sep 2020 19:29:25
User entered 'mupirocin'	Michele McCullough (b) (4)	18 Sep 2020 19:28:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:48:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:28:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:48:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 11:21:24
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'subject occasionally gets abrasions or scrapes. not considered medical history.' (Site from DM).	Michele McCullough (b) (4)	02 Dec 2020 15:21:49
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:31:40
User entered 'skin infection'	Michele McCullough (b) (4)	18 Sep 2020 19:28:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:48:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '2'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:28:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:48:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Other (OTHER)'	Michele McCullough (b) (4)	18 Sep 2020 19:28:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:48:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '%'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:28:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:48:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'as needed (PRN)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:28:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:48:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:28:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:48:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Topical (TOPICAL)'	Michele McCullough (b) (4)	18 Sep 2020 19:28:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:48:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:28:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:48:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'un UNK 2017'	Michele McCullough (b) (4)	18 Sep 2020 19:28:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:48:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:28:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:48:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Yes (Y)'	Michele McCullough (b) (4)	18 Sep 2020 19:28:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:48:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:28:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:48:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:28:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:48:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:28:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:28:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:28:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:48:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 19:35:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 19:35:39
Data point term sent to Coder	System	18 Sep 2020 19:34:42
User entered 'tamsulosin'	Michele McCullough (b) (4)	18 Sep 2020 19:34:33

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:48:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:34:33

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:48:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'urinary retention'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:34:33

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:48:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0.4'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:34:33

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:48:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'mg (mg)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:34:33

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:48:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:34:33

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:48:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'once daily (QD)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:34:33

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:48:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:34:33

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:48:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Oral (ORAL)'	Michele McCullough (b) (4)	18 Sep 2020 19:34:33

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:48:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:34:33

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'un UNK 2010'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:34:33

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:48:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:34:33

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:48:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Yes (Y)'	Michele McCullough (b) (4)	18 Sep 2020 19:34:33

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:48:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:34:33

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:48:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:34:33

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:48:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:34:33

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:34:33

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 19:34:33

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:48:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
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 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Sep 2020 19:37:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:37:46
Data point term sent to Coder	System	18 Sep 2020 19:36:47
User entered 'levothyroxine'	Michele McCullough (b) (4)	18 Sep 2020 19:36:27

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:48:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:36:27

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:48:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'hypothyroidism'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:36:27

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:48:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '112'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:36:27

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:48:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'ug (ug)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:36:27

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:48:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:36:27

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:48:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'once daily (QD)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:36:27

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:48:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:36:27

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:48:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Oral (ORAL)'	Michele McCullough (b) (4)	18 Sep 2020 19:36:27

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:48:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:36:27

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:48:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'un UNK 2016'	Michele McCullough (b) (4)	18 Sep 2020 19:36:27

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:48:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:36:27

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:48:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Yes (Y)'	Michele McCullough (b) (4)	18 Sep 2020 19:36:27

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:48:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:36:27

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:48:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:36:27

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:48:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:36:27

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:36:27

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 19:36:27

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:48:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM, PRODUCTSYNONYM: MOBIC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Sep 2020 19:38:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:38:36
Data point term sent to Coder	System	18 Sep 2020 19:37:49
User entered 'mobic'	Michele McCullough (b) (4)	18 Sep 2020 19:37:37

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:48:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:37:37

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:48:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
Query 'Per DM CLR: Please specify the location/type of Arthritis. Update Med History eCRF as appropriate. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 08:03:50
User opened query 'Per DM CLR: Please specify the location/type of Arthritis. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:32:08
User entered 'arthritis'	Michele McCullough (b) (4)	18 Sep 2020 19:37:37

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:48:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '15'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:37:37

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:48:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'mg (mg)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:37:37

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:48:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:37:37

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:48:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'other (OTHER)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:37:37

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:48:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '3 times per week'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:37:37

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:48:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Oral (ORAL)'	Michele McCullough (b) (4)	18 Sep 2020 19:37:37

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:48:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:37:37

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'un UNK 2010'	Michele McCullough (b) (4)	18 Sep 2020 19:37:37

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:48:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:37:37

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:48:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Yes (Y)'	Michele McCullough (b) (4)	18 Sep 2020 19:37:37

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:48:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:37:37

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:48:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:37:37

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:48:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:37:37

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:37:37

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:37:37

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:48:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: SILDENAFIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Sep 2020 19:39:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:39:39
Data point term sent to Coder	System	18 Sep 2020 19:38:54
User entered 'sildenafil'	Michele McCullough (b) (4)	18 Sep 2020 19:38:21

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:48:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:38:21

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:48:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'erectile dysfunction'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:38:21

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:48:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '100'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:38:21

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:48:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'mg (mg)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:38:21

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:48:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:38:21

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:48:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'as needed (PRN)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:38:21

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:48:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:38:21

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:48:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Oral (ORAL)'	Michele McCullough (b) (4)	18 Sep 2020 19:38:21

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:48:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:38:21

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'un UNK 2015'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:38:21

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:48:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:38:21

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:48:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:38:21

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:48:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:38:21

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:48:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:38:21

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:48:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:38:21

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:38:21

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:38:21

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:48:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 19:40:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 19:40:41
Data point term sent to Coder	System	18 Sep 2020 19:39:57
User entered 'multivitamin'	Michele McCullough (b) (4)	18 Sep 2020 19:39:15

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:48:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:39:15

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:48:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'health promotion'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:39:15

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:48:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'I'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:39:15

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:48:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'tablet (TABLET)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:39:15

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:48:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:39:15

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:48:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'once daily (QD)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:39:15

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:48:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:39:15

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:48:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Oral (ORAL)'	Michele McCullough (b) (4)	18 Sep 2020 19:39:15

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:48:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:39:15

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:48:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'un UNK 2000'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:39:15

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:48:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:39:15

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:48:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Yes (Y)'	Michele McCullough (b) (4)	18 Sep 2020 19:39:15

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:48:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:39:15

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:48:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:39:15

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:48:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:39:15

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:39:15

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 19:39:15

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:48:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Sep 2020 19:41:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:41:43
Data point term sent to Coder	System	18 Sep 2020 19:41:00
User entered 'tylenol'	Michele McCullough (b) (4)	18 Sep 2020 19:40:54

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:48:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:40:54

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:48:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
Query 'Per DM CLR: Please specify the location/type of Arthritis. Update Med History eCRF as appropriate. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 08:03:56
User opened query 'Per DM CLR: Please specify the location/type of Arthritis. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:32:27
User entered 'arthritis'	Michele McCullough (b) (4)	18 Sep 2020 19:40:54

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:48:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '500'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:40:54

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:48:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'mg (mg)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:40:54

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:48:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:40:54

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:48:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'as needed (PRN)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:40:54

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:48:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:40:54

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:48:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Oral (ORAL)'	Michele McCullough (b) (4)	18 Sep 2020 19:40:54

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:48:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:40:54

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'un UNK 2019'	Michele McCullough (b) (4)	18 Sep 2020 19:40:54

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:48:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:40:54

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:48:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:40:54

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:48:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:40:54

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:48:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	Michele McCullough (b) (4)	18 Sep 2020 19:40:54

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:48:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:40:54

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:40:54

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:40:54

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:48:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Sep 2020 19:42:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:42:46
Data point term sent to Coder	System	18 Sep 2020 19:42:02
User entered 'fexofenadine'	Michele McCullough (b) (4)	18 Sep 2020 19:41:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:48:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:41:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:48:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'seasonal allergies'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:41:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:48:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 11:21:37
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	Michele McCullough (b) (4)	02 Dec 2020 15:07:34
User entered '180' reason for change: Per Query Resolution	Michele McCullough (b) (4)	02 Dec 2020 15:07:30
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:33:42
User entered '1'	Michele McCullough (b) (4)	18 Sep 2020 19:41:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:48:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'mg (mg)' reason for change: Per Query Resolution	Michele McCullough (b) (4)	02 Dec 2020 15:07:30
User entered 'tablet (TABLET)'	Michele McCullough (b) (4)	18 Sep 2020 19:41:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:48:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:41:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:48:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'once daily (QD)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:41:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:48:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:41:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:48:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Oral (ORAL)'	Michele McCullough (b) (4)	18 Sep 2020 19:41:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:48:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:41:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'un UNK 2010'	Michele McCullough (b) (4)	18 Sep 2020 19:41:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:48:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:41:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:48:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:41:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:48:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:41:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:48:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:41:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:48:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:41:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:41:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 19:41:29

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:48:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
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.	(b) (4) Coder Import (b) (4)	18 Sep 2020 19:42:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:42:46
Data point term sent to Coder	System	18 Sep 2020 19:42:03
User entered 'pantoprazole'	Michele McCullough (b) (4)	18 Sep 2020 19:42:02

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:48:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:42:02

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:48:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'GERD'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:42:02

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:48:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '40'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:42:02

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:48:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'mg (mg)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:42:02

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:48:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:42:02

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:48:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'as needed (PRN)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:42:02

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:48:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:42:02

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:48:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Oral (ORAL)'	Michele McCullough (b) (4)	18 Sep 2020 19:42:02

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:48:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:42:02

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:48:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'un UNK 2015'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:42:02

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:48:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:42:02

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:48:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Yes (Y)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:42:02

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:48:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:42:02

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:48:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	18 Sep 2020 19:42:02

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:48:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:42:02

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:42:02

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:42:02

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:48:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 04:47:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 04:47:26
Data point term sent to Coder	System	20 Oct 2020 21:11:18
User entered 'seasonal influenza vaccine'	Michele McCullough (b) (4)	20 Oct 2020 21:10:41

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:48:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User closed query 'Per DM CLR: Prophylaxis = No. However, Vitamins, Supplements, Contraceptives and Vaccines are considered as Prophylaxis. Please review and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 06:00:07
Query 'Per DM CLR: Prophylaxis = No. However, Vitamins, Supplements, Contraceptives and Vaccines are considered as Prophylaxis. Please review and update accordingly. Otherwise, clarify.' answered with 'reviewed and updated' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	31 Dec 2020 18:24:59
User entered 'Yes (Y)' reason for change: Per Query Resolution	Sarah Bechnak (b) (4) (b) (4)	31 Dec 2020 18:24:54
User opened query 'Per DM CLR: Prophylaxis = No. However, Vitamins, Supplements, Contraceptives and Vaccines are considered as Prophylaxis. Please review and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 17:15:28
User entered 'No (N)'	Michele McCullough (b) (4)	20 Oct 2020 21:10:41

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:48:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'vaccination'	Michele McCullough (b) (4)	20 Oct 2020 21:10:41

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:48:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'I'	(b) (4) Michele McCullough	20 Oct 2020 21:10:41
	(b) (4)	

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:48:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Other (OTHER)'	Michele McCullough (b) (4)	20 Oct 2020 21:10:41

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:48:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'injection'	(b) (4) Michele McCullough (b) (4)	20 Oct 2020 21:10:41

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:48:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'once (ONCE)'	(b) (4) Michele McCullough	20 Oct 2020 21:10:41
	(b) (4)	

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:48:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough	20 Oct 2020 21:10:41
	(b) (4)	

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:48:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Michele McCullough (b) (4)	20 Oct 2020 21:10:41

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:48:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Michele McCullough	20 Oct 2020 21:10:41
	(b) (4)	

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:48:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '14 Oct 2020'	(b) (4) Michele McCullough	20 Oct 2020 21:10:41
	(b) (4)	

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:48:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	(b) (4) Michele McCullough	20 Oct 2020 21:10:41
	(b) (4)	

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:48:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough	20 Oct 2020 21:10:41
	(b) (4)	

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:48:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '14 Oct 2020'	(b) (4) Michele McCullough (b) (4)	20 Oct 2020 21:10:41

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:48:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Michele McCullough (b) (4)	20 Oct 2020 21:10:41

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:48:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:20
User entered empty.	System	20 Oct 2020 21:10:41

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:20
User entered empty.	System	20 Oct 2020 21:10:41

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:20
User entered empty.	System	20 Oct 2020 21:10:41

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:48:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 10:54:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 10:54:42
Data point term sent to Coder	System	16 Mar 2021 19:49:35
User entered 'Meloxicam'	(b) (4), (b) (6)	16 Mar 2021 19:49:34

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:48:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:49:34

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:48:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'arthritis muscle soreness'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:49:34

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:48:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '15'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:49:34

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:48:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:49:34

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:48:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:49:34

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:48:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:49:34

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:48:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:49:34

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:48:53

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 13:39:29
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'route is topical' (Site from DM).	Lauren Hewitt (b) (4)	08 Apr 2021 17:40:58
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 02:14:09
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	16 Mar 2021 19:49:34

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:48:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:49:34

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:48:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:49:34

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:48:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:49:34

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:48:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:49:34

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:48:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:49:34

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:48:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:49:34

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:48:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 19:49:34

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 19:49:34

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 19:49:34

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:48:53

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 19:24:14
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' answered with 'ongoing management of chronic hypertension' (Site from DM).	Mari Hart (b) (4)	09 Apr 2021 18:34:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Apr 2021 17:50:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Apr 2021 17:50:54
Data point term sent to Coder Coding entries removed.	System	08 Apr 2021 17:49:43
Signature has been broken.	Lauren Hewitt (b) (4)	08 Apr 2021 17:48:51
User entered 'AMLODiPINE' reason for change: Data Entry Error	Lauren Hewitt (b) (4)	08 Apr 2021 17:48:51
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 02:12:37

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:48:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Mar 2021 20:09:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 20:09:54
Data point term sent to Coder	System	16 Mar 2021 19:53:39
User entered 'amlodpine'	(b) (4), (b) (6)	16 Mar 2021 19:53:07

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:48:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:53:07

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:48:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'hypertension'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:53:07

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:48:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '2'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:53:07

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:48:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:53:07

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:48:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:53:07

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:48:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:53:07

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:48:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:53:07

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:48:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:53:07

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:48:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:53:07

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:48:53

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:53:07

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:48:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:53:07

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:48:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:53:07

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:48:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:53:07

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:48:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:53:07

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:48:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 19:53:07

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 19:53:07

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Mar 2021 19:53:07

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:48:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Mar 2021 19:06:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 19:06:51
Data point term sent to Coder Coding entries removed.	System Mari Hart (b) (4)	23 Mar 2021 19:06:03 23 Mar 2021 19:05:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Mar 2021 19:00:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 19:00:44
Data point term sent to Coder User entered 'tylenol'	System Mari Hart (b) (4)	23 Mar 2021 18:59:53 23 Mar 2021 18:59:52

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:48:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	Mari Hart (b) (4)	23 Mar 2021 18:59:52

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:48:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'LEFT ARM and shoulder PAIN'	(b) (4)	
reason for change: Data Entry Error	Mari Hart (b) (4)	23 Mar 2021 19:05:11
User entered 'left arm pain'	(b) (4)	
	Mari Hart (b) (4)	23 Mar 2021 18:59:52
	(b) (4)	

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:48:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '500'	Mari Hart (b) (4)	23 Mar 2021 18:59:52

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:48:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'mg (mg)'	(b) (4) Mari Hart (b) (4)	23 Mar 2021 18:59:52

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:48:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	Mari Hart (b) (4)	23 Mar 2021 18:59:52

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:48:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'as needed (PRN)'	Mari Hart (b) (4)	23 Mar 2021 18:59:52

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:48:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Mari Hart (b) (4)	23 Mar 2021 18:59:52

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:48:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Oral (ORAL)'	(b) (4) Mari Hart (b) (4)	23 Mar 2021 18:59:52

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:48:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	Mari Hart (b) (4)	23 Mar 2021 18:59:52

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:48:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '7 Jan 2021'	Mari Hart (b) (4)	23 Mar 2021 18:59:52

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:48:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	Mari Hart (b) (4)	23 Mar 2021 18:59:52

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:48:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Mari Hart (b) (4)	23 Mar 2021 18:59:52

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:48:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '15 Feb 2021'	(b) (4) Mari Hart (b) (4)	23 Mar 2021 18:59:52

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:48:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	(b) (4) Mari Hart (b) (4)	23 Mar 2021 18:59:52

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:48:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:36
User entered empty.	System	23 Mar 2021 18:59:52

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:36
User entered empty.	System	23 Mar 2021 18:59:52

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:36
User entered empty.	System	23 Mar 2021 18:59:52

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:48:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:08
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 13:06:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 13:06:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 11:50:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 11:50:08
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	26 Mar 2021 22:31:21
Data point term sent to Coder	System	23 Mar 2021 19:19:25
User entered 'sodium chloride solution'	Mari Hart (b) (4) (b) (4)	23 Mar 2021 19:18:55

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:48:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	Mari Hart (b) (4)	23 Mar 2021 19:18:55

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:48:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'acute kidney injury'	(b) (4) Mari Hart (b) (4)	23 Mar 2021 19:18:55

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:48:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '1000'	(b) (4) Mari Hart (b) (4)	23 Mar 2021 19:18:55

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:48:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'mL (mL)'	Mari Hart (b) (4)	23 Mar 2021 19:18:55

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:48:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	Mari Hart (b) (4)	23 Mar 2021 19:18:55

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:48:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'once daily (QD)'	Mari Hart (b) (4)	23 Mar 2021 19:18:55

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:48:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Mari Hart (b) (4)	23 Mar 2021 19:18:55

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:48:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Mari Hart (b) (4)	23 Mar 2021 19:18:55

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:48:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	Mari Hart (b) (4)	23 Mar 2021 19:18:55

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:48:53

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '19 Jan 2021'	(b) (4) Mari Hart (b) (4)	23 Mar 2021 19:18:55

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:48:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '0'	Mari Hart (b) (4)	23 Mar 2021 19:18:55

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:48:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	Mari Hart (b) (4)	23 Mar 2021 19:18:55

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:48:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '22 Jan 2021'	Mari Hart (b) (4)	23 Mar 2021 19:18:55

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:48:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'No (N)'	Mari Hart (b) (4)	23 Mar 2021 19:18:55

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:48:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:08
User entered '1'	System	23 Mar 2021 19:18:55

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:08
User entered '1'	System	23 Mar 2021 19:18:55

US3482240

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:48:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:22:08
User entered '804 (804)'	System	23 Mar 2021 19:18:55

US3482240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:48:53

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:54:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Joy Winters (b) (4)	23 Mar 2021 18:49:06
User entered 'No (N)'	(b) (4), (b) (6)	12 Feb 2021 14:30:28

US3482240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:48:53

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
User entered '22 Jan 2021'	Joy Winters (b) (4)	23 Mar 2021 19:02:46
	(b) (4)	

US3482240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:48:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'MRI'	(b) (4) Joy Winters (b) (4) (b) (4)	23 Mar 2021 19:02:46

US3482240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:48:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'Diagnostic (DIAGNOSTIC)'	Joy Winters (b) (4)	23 Mar 2021 19:02:46

US3482240

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:48:53

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	23 Mar 2021 19:02:46

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered		
'USA-US106-2021-MRNA-1273-P301000005'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Yes (Y)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Yes (Y)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:23:17
DataPoint Un-verified.	System	12 Apr 2021 13:23:17
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered 'Nadine'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Easton'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:23:17
DataPoint Un-verified.	System	12 Apr 2021 13:23:17
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered 'Rouphael'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Beshears'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered '500 Irvin Court'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
User entered '500 Irvin Court Suite 200'	Mari Hart (b) (4)	23 Mar 2021 18:45:26
	(b) (4)	

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
User entered 'Decatur'	Mari Hart (b) (4)	23 Mar 2021 18:45:26
	(b) (4)	

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'GA'	(b) (4) Mari Hart (b) (4) (b) (4)	23 Mar 2021 18:45:26

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered '30030'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
User entered '30032'	Mari Hart (b) (4)	23 Mar 2021 18:45:26
	(b) (4)	

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 15:34:14
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:51:27
User entered 'US'	System	20 Jan 2021 21:19:17

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Apr 2021 13:23:17
User entered '4'	System	17 Mar 2021 19:16:04
User entered '3'	System	19 Feb 2021 21:03:33
User entered '2'	System	25 Jan 2021 15:34:40
User entered '1'	System	20 Jan 2021 21:19:17

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered		
'USA-US106-2021-MRNA-1273-P301000005'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Yes (Y)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Yes (Y)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:23:17
DataPoint Un-verified.	System	12 Apr 2021 13:23:17
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered 'Nadine'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Easton'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:23:17
DataPoint Un-verified.	System	12 Apr 2021 13:23:17
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered 'Rouphael'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Beshears'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered '500 Irvin Court'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
User entered '500 Irvin Court Suite 200'	Mari Hart (b) (4)	23 Mar 2021 18:45:26
	(b) (4)	

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
User entered 'Decatur'	Mari Hart (b) (4)	23 Mar 2021 18:45:26
	(b) (4)	

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'GA'	(b) (4) Mari Hart (b) (4)	23 Mar 2021 18:45:26
	(b) (4)	

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered '30030'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
User entered '30032'	Mari Hart (b) (4)	23 Mar 2021 18:45:26
	(b) (4)	

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 15:34:14
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:51:27
User entered 'US'	System	20 Jan 2021 21:19:17

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Apr 2021 13:23:17
User entered '4'	System	17 Mar 2021 19:16:04
User entered '3'	System	19 Feb 2021 21:03:33
User entered '2'	System	25 Jan 2021 15:34:40
User entered '1'	System	20 Jan 2021 21:19:17

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:48:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:51:27
User entered '20/Jan/2021 21:19'	System	20 Jan 2021 21:19:17

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:48:53

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.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 15:34:14
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:51:27
User entered 'I'	(b) (4), (b) (6)	20 Jan 2021 21:19:17

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered		
'USA-US106-2021-MRNA-1273-P301000005'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Yes (Y)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Yes (Y)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:23:17
DataPoint Un-verified.	System	12 Apr 2021 13:23:17
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered 'Nadine'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Easton'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:23:17
DataPoint Un-verified.	System	12 Apr 2021 13:23:17
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered 'Rouphael'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Beshears'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered '500 Irvin Court'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
User entered '500 Irvin Court Suite 200'	Mari Hart (b) (4)	23 Mar 2021 18:45:26
	(b) (4)	

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
User entered 'Decatur'	Mari Hart (b) (4)	23 Mar 2021 18:45:26
	(b) (4)	

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'GA'	(b) (4) Mari Hart (b) (4)	23 Mar 2021 18:45:26
	(b) (4)	

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered '30030'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
User entered '30032'	Mari Hart (b) (4)	23 Mar 2021 18:45:26
	(b) (4)	

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 15:34:14
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:51:27
User entered 'US'	System	20 Jan 2021 21:19:17

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Apr 2021 13:23:17
User entered '4'	System	17 Mar 2021 19:16:04
User entered '3'	System	19 Feb 2021 21:03:33
User entered '2'	System	25 Jan 2021 15:34:40
User entered '1'	System	20 Jan 2021 21:19:17

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:48:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '25/Jan/2021 15:34'	(b) (4) System	25 Jan 2021 15:34:40

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:48:53

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.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:03:40
User entered 'I'	(b) (4), (b) (6)	25 Jan 2021 15:34:40

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered		
'USA-US106-2021-MRNA-1273-P301000005'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Yes (Y)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Yes (Y)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:23:17
DataPoint Un-verified.	System	12 Apr 2021 13:23:17
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered 'Nadine'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Easton'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:23:17
DataPoint Un-verified.	System	12 Apr 2021 13:23:17
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered 'Rouphael'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Beshears'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered '500 Irvin Court'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
User entered '500 Irvin Court Suite 200'	Mari Hart (b) (4)	23 Mar 2021 18:45:26
	(b) (4)	

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
User entered 'Decatur'	Mari Hart (b) (4)	23 Mar 2021 18:45:26
	(b) (4)	

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'GA'	(b) (4) Mari Hart (b) (4)	23 Mar 2021 18:45:26
	(b) (4)	

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered '30030'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
User entered '30032'	Mari Hart (b) (4)	23 Mar 2021 18:45:26
	(b) (4)	

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 15:34:14
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:51:27
User entered 'US'	System	20 Jan 2021 21:19:17

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Apr 2021 13:23:17
User entered '4'	System	17 Mar 2021 19:16:04
User entered '3'	System	19 Feb 2021 21:03:33
User entered '2'	System	25 Jan 2021 15:34:40
User entered '1'	System	20 Jan 2021 21:19:17

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:48:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '19/Feb/2021 16:03'	(b) (4) System	19 Feb 2021 21:03:33

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:48:53

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.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 21:03:40
User entered 'I'	(b) (4), (b) (6)	19 Feb 2021 21:03:33

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered		
'USA-US106-2021-MRNA-1273-P301000005'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Yes (Y)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Yes (Y)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:23:17
DataPoint Un-verified.	System	12 Apr 2021 13:23:17
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered 'Nadine'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Easton'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:23:17
DataPoint Un-verified.	System	12 Apr 2021 13:23:17
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered 'Rouphael'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Beshears'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered '500 Irvin Court'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
User entered '500 Irvin Court Suite 200'	Mari Hart (b) (4)	23 Mar 2021 18:45:26
	(b) (4)	

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
User entered 'Decatur'	Mari Hart (b) (4)	23 Mar 2021 18:45:26
	(b) (4)	

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
User entered 'GA'	Mari Hart (b) (4)	23 Mar 2021 18:45:26
	(b) (4)	

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered '30030'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
User entered '30032'	Mari Hart (b) (4)	23 Mar 2021 18:45:26
	(b) (4)	

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 15:34:14
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:51:27
User entered 'US'	System	20 Jan 2021 21:19:17

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Apr 2021 13:23:17
User entered '4'	System	17 Mar 2021 19:16:04
User entered '3'	System	19 Feb 2021 21:03:33
User entered '2'	System	25 Jan 2021 15:34:40
User entered '1'	System	20 Jan 2021 21:19:17

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:48:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered '17/Mar/2021 14:16'	(b) (4) System	17 Mar 2021 19:16:04

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:48:53

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.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:16:04

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered		
'USA-US106-2021-MRNA-1273-P301000005'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Yes (Y)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Yes (Y)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'No (N)'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:23:17
DataPoint Un-verified.	System	12 Apr 2021 13:23:17
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered 'Nadine'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Easton'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:23:17
DataPoint Un-verified.	System	12 Apr 2021 13:23:17
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered 'Rouphael'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:51:27
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 21:19:10
User entered 'Beshears'	System	20 Jan 2021 21:18:42

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered '500 Irvin Court'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
User entered '500 Irvin Court Suite 200'	Mari Hart (b) (4)	23 Mar 2021 18:45:26
	(b) (4)	

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
User entered 'Decatur'	Mari Hart (b) (4)	23 Mar 2021 18:45:26
	(b) (4)	

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
User entered 'GA'	Mari Hart (b) (4)	23 Mar 2021 18:45:26
	(b) (4)	

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
	(b) (4)	
Signature has been broken.	System	12 Apr 2021 13:23:17
User entered '30030'	System	12 Apr 2021 13:23:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
	(b) (4)	
User entered '30032'	Mari Hart (b) (4)	23 Mar 2021 18:45:26
	(b) (4)	

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:31:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:34:14
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:51:27
User entered 'US'	System	20 Jan 2021 21:19:17

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:48:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Apr 2021 13:23:17
User entered '4'	System	17 Mar 2021 19:16:04
User entered '3'	System	19 Feb 2021 21:03:33
User entered '2'	System	25 Jan 2021 15:34:40
User entered '1'	System	20 Jan 2021 21:19:17

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:48:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
User entered '12/Apr/2021 06:23'	(b) (4) System	12 Apr 2021 13:23:17

US3482240

Folder: SAE USA-US106-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:48:53

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.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 13:23:17