

US3482064 (Prod: Hope Clinic of The Emory Vaccine Center)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:49:45

All time stamps listed in this document are displayed in GMT

US3482064

Form: Participant Creation

Data signed: (b) (4) 01 Apr 2021 22:59:55

Generated On: 11 Aug 2021 22:49:45

[Participant ID](#)

US3482064

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

US3482064

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:17:26

Generated On: 11 Aug 2021 22:49:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 15:17:20

Generated On: 11 Aug 2021 22:49:45

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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 15:17:20

Generated On: 11 Aug 2021 22:49:45

Date of Informed Consent (<i>dd MMM yyyy</i>)	17 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 15:17:20

Generated On: 11 Aug 2021 22:49:45

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 15:17:21

Generated On: 11 Aug 2021 22:49:45

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 15:17:20

Generated On: 11 Aug 2021 22:49:45

Condition	GRAVES DISEASE
Start date (dd MMM yyyy)	UN UNK 1968
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1968
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1968
Start Year (derived)	1968
Stop Month and Year (derived)	JAN 1968
Stop Year (derived)	1968

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 15:17:20

Generated On: 11 Aug 2021 22:49:45

Condition	TONSILECTOMY AND ADENOIDECTOMY
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1980
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	JAN 1980
Stop Year (derived)	1980

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 15:17:20

Generated On: 11 Aug 2021 22:49:45

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 15:17:20

Generated On: 11 Aug 2021 22:49:45

Condition	OSTEOARTHRITIS
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 (5)

Data signed: (b) (4) 13 Feb 2021 15:17:20

Generated On: 11 Aug 2021 22:49:45

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 15:17:20

Generated On: 11 Aug 2021 22:49:45

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 1968
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 1968
Start Year (derived)	1968
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 15:17:20

Generated On: 11 Aug 2021 22:49:45

Condition	POST-MENOPAUSAL
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 15:17:26

Generated On: 11 Aug 2021 22:49:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 09:05
Height (xxx.x)	62 in
Weight (xxx.x)	105 lb
BMI (xxx.x)	19.24491 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:17:21

Generated On: 11 Aug 2021 22:49:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 15:17:20

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Date of assessment (*dd MMM yyyy*) 17 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2004

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 15:17:26

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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 15:17:26

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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 15:17:26

Generated On: 11 Aug 2021 22:49:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 15:17:26

Generated On: 11 Aug 2021 22:49:45

What was the date of randomization? (dd MMM yyyy) 17 AUG 2020

What was the participant's randomization number? 186392

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 15:17:26

Generated On: 11 Aug 2021 22:49:45

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 15:17:26

Generated On: 11 Aug 2021 22:49:45

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)	17 AUG 2020
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 09:05
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 15:17:26

Generated On: 11 Aug 2021 22:49:45

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)	17 AUG 2020
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 11:30
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 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 15:17:26

Generated On: 11 Aug 2021 22:49:45

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 15:17:26

Generated On: 11 Aug 2021 22:49:45

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) 17 AUG 2020

What was the treatment time? (00:00-23:59) 10:56 (24 HR)

Treatment Date and Time (derived) 17 AUG 2020 10:56

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 15:17:26

Generated On: 11 Aug 2021 22:49:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 AUG 2020
Collection time (00:00-23:59)	10:00 (24 HR)
Collection date and time (derived)	17 AUG 2020 10:00

US3482064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 15:17:26

Generated On: 11 Aug 2021 22:49:45

Collection date (dd MMM yyyy)			17 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:05	17 AUG 2020 10:05
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:17:26

Generated On: 11 Aug 2021 22:49:45

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: 11 Aug 2021 22:49:45

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

17 AUG 2020 11:37

PC Open Date & Time

17 AUG 2020 11:16

PC Close Date & Time

17 AUG 2020 13:46

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °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	17 AUG 2020 18:34
PC Open Date & Time	17 AUG 2020 14:41
PC Close Date & Time	18 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

18 AUG 2020 18:27

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 18:21

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 18:20

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 18:37

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 18:24

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:45

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

97.5 °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

23 AUG 2020 18:26

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

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

17 AUG 2020 11:38

PC Open Date & Time

17 AUG 2020 11:16

PC Close Date & Time

17 AUG 2020 13:46

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

2

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

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

Yes ☐

No ☒

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

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

17 AUG 2020 18:37

PC Open Date & Time

17 AUG 2020 14:41

PC Close Date & Time

18 AUG 2020 11:59

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

2

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

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

Yes ☒

No ☐

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

30

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 18:31

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:45

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

20

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 18:22

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:45

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

20 AUG 2020 18:21

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:45

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

21 AUG 2020 18:38

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:45

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

22 AUG 2020 18:24

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:45

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

23 AUG 2020 18:27

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 11:39
PC Open Date & Time	17 AUG 2020 11:16
PC Close Date & Time	17 AUG 2020 13:46

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 18:38
PC Open Date & Time	17 AUG 2020 14:41
PC Close Date & Time	18 AUG 2020 11:59

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:45

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 ☒

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:45

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 18:34
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:45

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)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:45

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 18:23
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:45

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 ☒

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:45

		Yes <input type="checkbox"/>
PC Time stamp	20 AUG 2020 18:23	
PC Open Date & Time	20 AUG 2020 12:00	
PC Close Date & Time	21 AUG 2020 11:59	

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:45

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 18:39
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:45

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 18:25
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 1808

EAB) (1725)

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:45

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 18:28
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3482064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:17:20

Generated On: 11 Aug 2021 22:49:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482064

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:17:20

Generated On: 11 Aug 2021 22:49:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:17:20

Generated On: 11 Aug 2021 22:49:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482064

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:17:20

Generated On: 11 Aug 2021 22:49:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:17:20

Generated On: 11 Aug 2021 22:49:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482064

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:17:20

Generated On: 11 Aug 2021 22:49:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482064

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:17:27

Generated On: 11 Aug 2021 22:49:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 15:17:27

Generated On: 11 Aug 2021 22:49:45

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	08:45 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 08:45
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)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 15:17:27

Generated On: 11 Aug 2021 22:49:45

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
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 <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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	

US3482064

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:17:27

Generated On: 11 Aug 2021 22:49:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3482064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 15:17:27

Generated On: 11 Aug 2021 22:49:45

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?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3482064

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:17:27

Generated On: 11 Aug 2021 22:49:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 SEP 2020

Collection time (00:00-23:59)

09:05 (24 HR)

Collection date and time (derived)

14 SEP 2020 09:05

US3482064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 15:17:26

Generated On: 11 Aug 2021 22:49:45

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:05	14 SEP 2020 09:05
Nasopharyngeal Swab 2	No		

US3482064

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:17:27

Generated On: 11 Aug 2021 22:49:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:17:20

Generated On: 11 Aug 2021 22:49:45

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

US3482064

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:17:20

Generated On: 11 Aug 2021 22:49:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:17:20

Generated On: 11 Aug 2021 22:49:45

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

US3482064

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:17:20

Generated On: 11 Aug 2021 22:49:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:17:20

Generated On: 11 Aug 2021 22:49:45

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

US3482064

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:17:20

Generated On: 11 Aug 2021 22:49:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482064

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:17:27

Generated On: 11 Aug 2021 22:49:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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

US3482064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 15:17:27

Generated On: 11 Aug 2021 22:49:45

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) _____

US3482064

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:17:27

Generated On: 11 Aug 2021 22:49:45

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.

US3482064

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:17:27

Generated On: 11 Aug 2021 22:49:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 OCT 2020

Collection time (00:00-23:59)

08:35 (24 HR)

Collection date and time (derived)

12 OCT 2020 08:35

US3482064

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:17:27

Generated On: 11 Aug 2021 22:49:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 18:20:27

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

26 OCT 2020 18:37:05

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

02 NOV 2020 22:12:37

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 21:24:42

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 NOV 2020 13:22:02

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

25 NOV 2020 16:51:30

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 DEC 2020 17:15:13
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

09 DEC 2020 08:26:15

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 DEC 2020 15:42:19
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

23 DEC 2020 00:03:01

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 13:17:31

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 JAN 2021 16:31:15
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

15 JAN 2021 11:24:00

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 <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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	20 JAN 2021 13:26:52
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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	27 JAN 2021 11:34:21
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

03 FEB 2021 17:00:47

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 08:00:02
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

17 FEB 2021 09:45:29

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 FEB 2021 21:41:55
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAR 2021 00:37:44
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

10 MAR 2021 12:02:31

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

17 MAR 2021 10:45:06

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

24 MAR 2021 14:58:35

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

31 MAR 2021 00:44:03

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

07 APR 2021 03:12:11

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

14 APR 2021 01:09:49

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 17:49:48

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 15:46:56

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 <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"/>

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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°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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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"/>

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 348

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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="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"/>

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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"/>

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 <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"/>

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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"/>

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 DEC 2021 00:01
Patient Cloud Close Date & Time	12 DEC 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 488

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

15 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 DEC 2021 00:01
Patient Cloud Close Date & Time	26 DEC 2021 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 JAN 2022 00:01
Patient Cloud Close Date & Time	23 JAN 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 607

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

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

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

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

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

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

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 614

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 670

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

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

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

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

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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"/>

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JUL 2022 00:01
Patient Cloud Close Date & Time	17 JUL 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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°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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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°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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 ☐

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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"/>

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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

Date and time of submission	
Patient Cloud Open Date & Time	19 OCT 2022 00:01
Patient Cloud Close Date & Time	23 OCT 2022 23:59

US3482064

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:49:45

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		28 FEB 2021 11:46:15

US3482064

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:00:05

Generated On: 11 Aug 2021 22:49:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482064

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 22:59:55

Generated On: 11 Aug 2021 22:49:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482064

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 22:59:55

Generated On: 11 Aug 2021 22:49:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482064

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 22:59:55

Generated On: 11 Aug 2021 22:49:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482064

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 22:59:55

Generated On: 11 Aug 2021 22:49:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482064

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 22:59:55

Generated On: 11 Aug 2021 22:49:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482064

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 22:59:55

Generated On: 11 Aug 2021 22:49:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482064

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 22:59:55

Generated On: 11 Aug 2021 22:49:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482064

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:00:05

Generated On: 11 Aug 2021 22:49:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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

US3482064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

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

US3482064

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:00:05

Generated On: 11 Aug 2021 22:49:45

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.

US3482064

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 23:00:05

Generated On: 11 Aug 2021 22:49:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 MAR 2021
Collection time (00:00-23:59)	10:27 (24 HR)
Collection date and time (derived)	12 MAR 2021 10:27

US3482064

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:00:05

Generated On: 11 Aug 2021 22:49:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482064

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 16:18:47

Generated On: 11 Aug 2021 22:49:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482064

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 16:18:47

Generated On: 11 Aug 2021 22:49:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482064

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

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

US3482064

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3482064

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:49:45

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"/>

US3482064

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:49:45

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3482064

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

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 22:59:55

Generated On: 11 Aug 2021 22:49:45

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

Visit date (dd MMM yyyy)	8 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3482064

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 16:10:14

Generated On: 11 Aug 2021 22:49:45

Date of updated informed consent (<i>dd MMM yyyy</i>)	8 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	8 JAN 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3482064

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 01 Apr 2021 22:59:55

Generated On: 11 Aug 2021 22:49:45

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

US3482064

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 22:59:55

Generated On: 11 Aug 2021 22:49:45

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 JAN 2021
Time of assessment (00:00-23:59)	13:56 (24 HR)
Vital Signs Date and Time (derived)	08 JAN 2021 13:56
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3482064

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 22:59:55

Generated On: 11 Aug 2021 22:49:45

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 JAN 2021
Time of assessment (00:00-23:59)	15:58 (24 HR)
Vital Signs Date and Time (derived)	08 JAN 2021 15:58
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3482064

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

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 22:59:55

Generated On: 11 Aug 2021 22:49:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 JAN 2021

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

US3482064

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

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 22:59:55

Generated On: 11 Aug 2021 22:49:45

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 08 JAN 2021

What was the treatment time? (00:00-23:59) 15:28 (24 HR)

Treatment Date and Time (derived) 08 JAN 2021 15:28

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

US3482064

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 22:59:55

Generated On: 11 Aug 2021 22:49:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 JAN 2021

Collection time (00:00-23:59)

13:49 (24 HR)

Collection date and time (derived)

8 JAN 2021 13:49

US3482064

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 01 Apr 2021 22:59:55

Generated On: 11 Aug 2021 22:49:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 JAN 2021
Collection time (00:00 - 23:59)	13:53
Collection Date and Time (derived)	8 JAN 2021 13:53

US3482064

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

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 22:59:55

Generated On: 11 Aug 2021 22:49:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482064

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:00:05

Generated On: 11 Aug 2021 22:49:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482064

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:00:05

Generated On: 11 Aug 2021 22:49:45

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

US3482064

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 22:59:55

Generated On: 11 Aug 2021 22:49:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3482064

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 22:59:55

Generated On: 11 Aug 2021 22:49:45

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) _____

US3482064

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 22:59:55

Generated On: 11 Aug 2021 22:49:45

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.

US3482064

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 22:59:55

Generated On: 11 Aug 2021 22:49:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 FEB 2021
Collection time (00:00-23:59)	13:50 (24 HR)
Collection date and time (derived)	4 FEB 2021 13:50

US3482064

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 03:13:07

Generated On: 11 Aug 2021 22:49:45

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 03:13:06

Generated On: 11 Aug 2021 22:49:45

AEID

Adverse event

NON-URTICARIAL MACULAR
RASH WITH BLANCHING
ERYTHEMA ON LEFT DELTOID

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)

25 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

04 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 03:13:06

Generated On: 11 Aug 2021 22:49:45

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input 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	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 03:13:06

Generated On: 11 Aug 2021 22:49:45

71 YO FEMALE WHO RECEIVED
INVESTIGATIONAL PRODUCT
IN LEFT DELTOID ON 8/17/20.
SHE HAD NO SYMPTOMS FOR 7
DAYS BUT ON DAY 8 NOTED
AN AREA OF ERYTHEMA ON
LEFT UPPER ARM APPROX 3 CM
IN SIZE. THIS PROGRESSIVELY
ENLARGED AND BECAME
INDURATED AND WARM
WITHOUT PAIN OR PRURITIS.
ON EVALUATION DAY 15
THERE WAS A 12 X5 CM WELL
CIRCUMSCRIBED RASH OVER
THE LEFT ANTERIOR UPPER
ARM, SPARSELY
ERYTHEMATOUS SUPERIORLY
WITH BLANCHING ERYTHEMA
AND SLIGHT INDURATION. NO
AXILLARY ADENOPATHY.
GIVEN LOCATION OF THE RASH
IT IS PROBABLY RELATED TO
THE STUDY DRUG AND COULD
REPRESENT A DELAYED
HYPERSENSITIVITY
REACTION.

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Mar 2021 22:21:32

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Mar 2021 22:21:32

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Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 88

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) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

	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 DEC 1968	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

	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 (3)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

Name of Medication CALCIUM/VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication OSTEOPENIA

Dose per administration 600/800

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

If dose unit is Other, specify MG/IU

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) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

Name of Medication VITAMIN B-12

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Mar 2021 22:21:32

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Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE REDNESS ON
LEFT ARM AT VACCINE SITE
(NON-URTICARIAL MACULAR
RASH WITH BLANCHING
ERYTHEMA ON LEFT DELTOID)

Dose per administration 25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	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"/>
<hr/>		
If route of administration is Other, specify _____		
<hr/>		
Start date (dd MMM yyyy)		03 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		03 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)		802 <input type="checkbox"/>
		803 <input type="checkbox"/>
		804 <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

Name of Medication SEASONAL INFLUENZA
VACCINE

Prophylaxis Yes ☒
No ☐

Indication SEASONAL FLU PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	09 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

Name of Medication SCOPOLAMINE

Prophylaxis Yes ☐
No ☒

Indication ANTI-NAUSEA

Dose per administration 1.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

	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)		14 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) 14 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

Name of Medication PROPAPOL

Prophylaxis Yes ☐
No ☒

Indication ANESTHETIC

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 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)		14 JAN 2021
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication ANESTHETIC

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 (9)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 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)		14 JAN 2021
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

Name of Medication SEROFLUANE

Prophylaxis Yes ☐
No ☒

Indication ANESTHETIC

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 (10)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 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)		14 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

Name of Medication LIDOCAINE

Prophylaxis Yes ☐
No ☒

Indication ANESTHETIC

Dose per administration 60

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) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 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)		14 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication ANTI-NAUSEA

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

	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)	14 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)		24 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

Name of Medication OXYCODONE/ACETAMINOPHE
N

Prophylaxis Yes ☐
No ☒

Indication PAIN MANAGEMENT

Dose per administration 5-325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

Name of Medication EXTRA STRENGTH TYLENOL

Prophylaxis Yes ☐
No ☒

Indication PAIN MANAGEMENT

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 (14)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 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)	_____	
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 (15)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐
No ☒

Indication MUSCLE RELAXER

Dose per administration 375

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 (15)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

	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)	14 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)		24 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

Name of Medication DURICEF

Prophylaxis Yes ☒
No ☐

Indication ANTIBIOTIC

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 (16)

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

	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)	14 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)	28 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3482064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Mar 2021 22:21:32

Generated On: 11 Aug 2021 22:49:45

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
14 JAN 2021	BILATERAL EXPLANT SURGERY	Other	ELECTIVE SURGERY

US3482064

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 01 Apr 2021 22:59:55

Generated On: 11 Aug 2021 22:49:45

Date of dosing discontinuation (dd MMM yyyy) 14 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input checked="" type="radio"/>
SAE (specify)	<input type="radio"/>
Death	<input type="radio"/>
Lost To Follow-up	<input type="radio"/>
Physician decision (specify)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Protocol deviation (specify)	<input type="radio"/>
Study Terminated By Sponsor	<input type="radio"/>
Withdrawal of consent by participant (specify)	<input type="radio"/>
Due to SARS-COV-2	<input type="radio"/>
Other	<input type="radio"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify AE#1

US3482064

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:49:45

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 ☐

Audit

US3482064 (Prod: Hope Clinic of The Emory Vaccine Center)

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US3482064

Form: Participant Creation

Generated On: 11 Aug 2021 22:49:45

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'US3482064'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 12:59:47

US3482064

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:38:51

US3482064

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '17 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 12:59:48

US3482064

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

[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 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:38:51

US3482064

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered 'SCRN'	System	17 Aug 2020 15:38:51

US3482064

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:45

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered (b) (6) 1948'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 12:59:48

US3482064

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:45

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '71'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:39:10

US3482064

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:45

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered 'YEARS'	System	17 Aug 2020 15:39:10

US3482064

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:45

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered '71'	System	17 Aug 2020 15:35:18

US3482064

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:45

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:39:10

US3482064

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:45

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:39:10

US3482064

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:45

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:39:10

US3482064

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:45

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:39:10

US3482064

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:45

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:39:10

US3482064

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:45

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:39:10

US3482064

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:45

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:39:10

US3482064

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:39:10

US3482064

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:45

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:39:10

US3482064

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:45

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:39:10

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Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:45

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:39:10

US3482064

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:45

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:35:18

US3482064

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered 'Aug 2020'	System	17 Aug 2020 15:35:18

US3482064

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered '2020'	System	17 Aug 2020 15:35:18

US3482064

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:45

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'Amendment 1 (1)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:35:18

US3482064

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:35:18

US3482064

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:45

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:35:18

US3482064

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:45

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:35:18

US3482064

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:45

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:35:18

US3482064

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:45

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 12:59:48

US3482064

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:45

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered 'I'	System	17 Aug 2020 15:35:18

US3482064

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:34:48

US3482064

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:49:45

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:39:21

US3482064

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hyperfunction disorders, PT: Basedow's disease, LLT: Graves' disease - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 22:23:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 22:23:23
Data point term sent to Coder	System	17 Aug 2020 22:22:39
User entered 'graves disease'	(b) (4), (b) (6)	17 Aug 2020 22:22:03

US3482064

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'un UNK 1968'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:22:03

US3482064

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:22:03

US3482064

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:22:03

US3482064

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'un UNK 1968'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:22:03

US3482064

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:22:03

US3482064

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered 'Jan 1968'	System	17 Aug 2020 22:22:03

US3482064

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered '1968'	System	17 Aug 2020 22:22:03

US3482064

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered 'Jan 1968'	System	17 Aug 2020 22:22:03

US3482064

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered '1968'	System	17 Aug 2020 22:22:03

US3482064

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Adenotonsillectomy, LLT: Tonsillectomy & Adenoidectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	18 Aug 2020 07:01:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:01:19
Data point term sent to Coder	System	17 Aug 2020 22:23:39
User entered 'Tonsilectomy and Adenoidectomy'	(b) (4), (b) (6)	17 Aug 2020 22:22:54

US3482064

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'un UNK 1980'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:22:54

US3482064

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:22:54

US3482064

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:22:54

US3482064

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'un UNK 1980'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:22:54

US3482064

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:22:54

US3482064

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered 'Jan 1980'	System	17 Aug 2020 22:22:54

US3482064

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered '1980'	System	17 Aug 2020 22:22:54

US3482064

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered 'Jan 1980'	System	17 Aug 2020 22:22:54

US3482064

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered '1980'	System	17 Aug 2020 22:22:54

US3482064

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Aug 2020 22:24:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 22:24:25
Data point term sent to Coder	System	17 Aug 2020 22:23:39
User entered 'osteopenia'	(b) (4), (b) (6)	17 Aug 2020 22:23:18

US3482064

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:23:18

US3482064

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:23:18

US3482064

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:23:18

US3482064

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:23:18

US3482064

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:23:18

US3482064

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered 'Jan 2018'	System	17 Aug 2020 22:23:18

US3482064

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered '2018'	System	17 Aug 2020 22:23:18

US3482064

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered empty.	System	17 Aug 2020 22:23:18

US3482064

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered empty.	System	17 Aug 2020 22:23:18

US3482064

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	18 Aug 2020 07:25:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:25:31
Data point term sent to Coder	System	17 Aug 2020 22:24:40
User entered 'osteoarthritis'	(b) (4), (b) (6)	17 Aug 2020 22:24:07

US3482064

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:24:07

US3482064

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:24:07

US3482064

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:24:07

US3482064

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:24:07

US3482064

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:24:07

US3482064

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered 'Jan 2015'	System	17 Aug 2020 22:24:07

US3482064

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered '2015'	System	17 Aug 2020 22:24:07

US3482064

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered empty.	System	17 Aug 2020 22:24:07

US3482064

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered empty.	System	17 Aug 2020 22:24:07

US3482064

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Breast therapeutic procedures NEC, PT: Mammoplasty, LLT: Breast prosthesis implantation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Aug 2020 22:26:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 22:26:12
Data point term sent to Coder	System	17 Aug 2020 22:25:41
User entered 'BREAST Implants' reason for change:	(b) (4), (b) (6)	17 Aug 2020 22:24:44
Data Entry Error		
Data point term sent to Coder	System	17 Aug 2020 22:24:40
User entered 'breast impants'	(b) (4), (b) (6)	17 Aug 2020 22:24:26

US3482064

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:24:26

US3482064

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:24:26

US3482064

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:57:58
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:27:07
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	08 Oct 2020 14:26:59
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	08 Oct 2020 14:26:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:26:46
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 08:56:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 22:24:26

US3482064

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:24:26

US3482064

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:26:59
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 22:24:26

US3482064

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered empty.	System	17 Aug 2020 22:24:26

US3482064

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered empty.	System	17 Aug 2020 22:24:26

US3482064

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered empty.	System	17 Aug 2020 22:24:26

US3482064

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered empty.	System	17 Aug 2020 22:24:26

US3482064

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
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)	15 Oct 2020 18:36:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 18:36:30
Data point term sent to Coder	System	15 Oct 2020 18:35:56
User entered 'hypothyroidism'	(b) (4), (b) (6)	15 Oct 2020 18:35:15

US3482064

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered 'un UNK 1968' reason for change:	System	15 Oct 2020 18:35:23
Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 18:35:23
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).		
User entered ' UNK 1968' (non-conformant).	System	15 Oct 2020 18:35:15
	(b) (4), (b) (6)	15 Oct 2020 18:35:15

US3482064

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 18:35:15

US3482064

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 18:35:15

US3482064

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 18:35:15

US3482064

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 18:35:15

US3482064

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered 'Jan 1968'	System	15 Oct 2020 18:35:23
User entered empty.	System	15 Oct 2020 18:35:15

US3482064

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered '1968'	System	15 Oct 2020 18:35:23
User entered empty.	System	15 Oct 2020 18:35:15

US3482064

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered empty.	System	15 Oct 2020 18:35:15

US3482064

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered empty.	System	15 Oct 2020 18:35:15

US3482064

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Oct 2020 16:56:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 16:56:36
Data point term sent to Coder	System	23 Oct 2020 16:55:38
User entered 'post-menopausal'	(b) (4), (b) (6)	23 Oct 2020 16:54:52

US3482064

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'un UNK 2004'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:54:52

US3482064

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:54:52

US3482064

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:54:52

US3482064

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:54:52

US3482064

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:54:52

US3482064

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered 'Jan 2004'	System	23 Oct 2020 16:54:52

US3482064

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered '2004'	System	23 Oct 2020 16:54:52

US3482064

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered empty.	System	23 Oct 2020 16:54:52

US3482064

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered empty.	System	23 Oct 2020 16:54:52

US3482064

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:33:10

US3482064

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:33:10

US3482064

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '09:05'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:33:10

US3482064

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered '17 Aug 2020 09:05'	System	17 Aug 2020 17:33:10

US3482064

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '62' in	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:33:10
DataPoint set to visible.	System	17 Aug 2020 15:35:18

US3482064

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '105' lb	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:33:10
DataPoint set to visible.	System	17 Aug 2020 15:35:18

US3482064

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
Amendment Manager: User entered '19.24491'	System	16 Sep 2020 23:59:24
User entered '19.2'	System	17 Aug 2020 17:33:10
DataPoint set to visible.	System	17 Aug 2020 15:35:18

US3482064

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered 'kg/m2'	System	17 Aug 2020 17:33:10
DataPoint set to visible.	System	17 Aug 2020 15:35:18

US3482064

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 06:13:47
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update accordingly.' answered with 'ND added' (Site from DM).	Amy Anderson (b) (4) (b) (4)	25 Sep 2020 17:01:48
User entered missing code ND - Not Done; reason for change Per Query Resolution	Amy Anderson (b) (4) (b) (4)	25 Sep 2020 17:00:27
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 19:19:01
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:34:35
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	17 Aug 2020 17:34:35
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 17:34:35
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:33:10
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:33:10

US3482064

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty; reason for change Per Query Resolution	(b) (4) Amy Anderson (b) (4)	25 Sep 2020 17:00:27
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:34:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).		17 Aug 2020 17:34:35
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 17:34:35
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 17:33:10
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:33:10

US3482064

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:33:10

US3482064

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	25 Sep 2020 17:00:27
User closed query 'Data is required. Please provide.' (Site from System).	Amy Anderson (b) (4)	17 Aug 2020 17:34:35
Query 'Data is required. Please provide.' answered by data change (Site from System).	(b) (4)	17 Aug 2020 17:34:35
User entered '74' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 17:34:35
User opened query 'Data is required. Please provide.' (Site from System).		17 Aug 2020 17:33:10
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:33:10

US3482064

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered 'bpm'	System	17 Aug 2020 17:34:35
User entered empty.	System	17 Aug 2020 17:33:10

US3482064

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	25 Sep 2020 17:00:27
User closed query 'Data is required. Please provide.' (Site from System).	Amy Anderson (b) (4)	17 Aug 2020 17:34:35
Query 'Data is required. Please provide.' answered by data change (Site from System).	(b) (4)	17 Aug 2020 17:34:35
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 17:34:35
User opened query 'Data is required. Please provide.' (Site from System).		17 Aug 2020 17:33:10
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:33:10

US3482064

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered 'breaths/min'	System	17 Aug 2020 17:34:35
User entered empty.	System	17 Aug 2020 17:33:10

US3482064

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	25 Sep 2020 17:00:27
User closed query 'Data is required. Please provide.' (Site from System).	Amy Anderson (b) (4)	17 Aug 2020 17:34:35
Query 'Data is required. Please provide.' answered by data change (Site from System).	(b) (4)	17 Aug 2020 17:34:35
User entered '139' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 17:34:35
User opened query 'Data is required. Please provide.' (Site from System).		17 Aug 2020 17:33:10
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:33:10

US3482064

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered 'mmHg'	System	17 Aug 2020 17:34:35
User entered empty.	System	17 Aug 2020 17:33:10

US3482064

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	25 Sep 2020 17:00:27
User closed query 'Data is required. Please provide.' (Site from System).	Amy Anderson (b) (4)	17 Aug 2020 17:34:35
Query 'Data is required. Please provide.' answered by data change (Site from System).	(b) (4)	17 Aug 2020 17:34:35
User entered '73' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 17:34:35
User opened query 'Data is required. Please provide.' (Site from System).		17 Aug 2020 17:33:10
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:33:10

US3482064

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User entered 'mmHg'	System	17 Aug 2020 17:34:35
User entered empty.	System	17 Aug 2020 17:33:10

US3482064

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06

US3482064

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06

US3482064

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:34:57

US3482064

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:21:21
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 17:48:40
User entered '17 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 17:34:57

US3482064

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:49:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:35:13

US3482064

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:35:13

US3482064

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:49:45

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 09:53:14
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. answered with 'added to MH per request' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 16:55:08
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 05:40:13
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	17 Aug 2020 17:35:13

US3482064

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:49:45

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:35:13

US3482064

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:35:13

US3482064

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:49:45

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:35:13

US3482064

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User closed query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	(b) (4)	
User entered 'un UNK 2004' reason for change:	System	17 Aug 2020 17:35:41
Data Entry Error		
User opened query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	System	17 Aug 2020 17:35:13
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:35:13

US3482064

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:49:45

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:35:13

US3482064

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:45

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 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:13

US3482064

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:45

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 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:13

US3482064

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:45

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 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:13

US3482064

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:45

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 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:13

US3482064

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:45

[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 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:13

US3482064

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:45

[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 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:13

US3482064

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:45

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 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:13

US3482064

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:45

[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 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:13

US3482064

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:45

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 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:13

US3482064

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:45

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 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:13

US3482064

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:45

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 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:13

US3482064

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:45

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:13

US3482064

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:45

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User closed query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	(b) (4)	17 Aug 2020 17:38:18
User entered '0' reason for change: Data Entry Error	System	17 Aug 2020 17:38:18
User opened query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 17:38:13
User entered '1'	System	17 Aug 2020 17:38:13

US3482064

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:13

US3482064

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:45

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 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:13

US3482064

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:45

[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 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:13

US3482064

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:45

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 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:13

US3482064

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:13

US3482064

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:13

US3482064

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:45

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'resident in a community with ongoing person to person transmission'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:38:13

US3482064

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:34:32

US3482064

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:34:32

US3482064

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

[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 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:34:32

US3482064

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User entered 'VISIT1'	System	17 Aug 2020 15:34:32

US3482064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '17 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 14:24:34

US3482064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:56:22
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:56:21
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 14:24:34
User entered '186392' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 14:24:34

US3482064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 14:24:34

US3482064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:45

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 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:34:12

US3482064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:45

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 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:34:12

US3482064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:34:12

US3482064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:45

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:34:12

US3482064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:45

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:34:12

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:45

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
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 accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 11:25:40
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 accordingly.' answered with 'added ND' (Site from DM).	Amy Anderson (b) (4) (b) (4)	25 Sep 2020 16:55:04
User entered missing code ND - Not Done; reason for change Data Entry Error	Amy Anderson (b) (4) (b) (4)	25 Sep 2020 16:54:47
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 accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 19:19:12
User entered '62' in	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:45

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 16:54:47
User entered '105' lb	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:45

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
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 accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 11:25:40
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 accordingly.' answered with 'added ND' (Site from DM).	Amy Anderson (b) (4) (b) (4)	25 Sep 2020 16:55:04
User entered missing code ND - Not Done; reason for change Data Entry Error	Amy Anderson (b) (4) (b) (4)	25 Sep 2020 16:54:47
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 accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 19:19:12
User entered '62' in	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:45

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 16:54:47
User entered '105' lb	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 12:57:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 12:57:09
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 17:31:58
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '17 Aug 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Aug 2020 12:57:09
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '09:05' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Aug 2020 12:57:09
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User entered '17 Aug 2020 09:05'	System	31 Aug 2020 12:57:09
User entered empty.	System	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '98.1' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Aug 2020 12:57:09
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Aug 2020 12:57:09
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '74' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Aug 2020 12:57:09
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User entered 'bpm'	System	31 Aug 2020 12:57:09
User entered empty.	System	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '16' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Aug 2020 12:57:09
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User entered 'breaths/min'	System	31 Aug 2020 12:57:09
User entered empty.	System	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '139' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Aug 2020 12:57:09
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User entered 'mmHg'	System	31 Aug 2020 12:57:09
User entered empty.	System	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '73' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Aug 2020 12:57:09
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User entered 'mmHg'	System	31 Aug 2020 12:57:09
User entered empty.	System	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:45

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
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 accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 11:25:40
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 accordingly.' answered with 'added ND' (Site from DM).	Amy Anderson (b) (4) (b) (4)	25 Sep 2020 16:55:04
User entered missing code ND - Not Done; reason for change Data Entry Error	Amy Anderson (b) (4) (b) (4)	25 Sep 2020 16:54:47
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 accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 19:19:12
User entered '62' in	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:45

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 16:54:47
User entered '105' lb	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 12:57:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 12:57:09
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 17:31:58
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '17 Aug 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Aug 2020 12:57:09
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '11:30' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Aug 2020 12:57:09
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User entered '17 Aug 2020 11:30'	System	31 Aug 2020 12:57:09
User entered empty.	System	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '97.1' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Aug 2020 12:57:09
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Aug 2020 12:57:09
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '72' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Aug 2020 12:57:09
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User entered 'bpm'	System	31 Aug 2020 12:57:09
User entered empty.	System	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '16' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Aug 2020 12:57:09
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User entered 'breaths/min'	System	31 Aug 2020 12:57:09
User entered empty.	System	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '134' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Aug 2020 12:57:09
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User entered 'mmHg'	System	31 Aug 2020 12:57:09
User entered empty.	System	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '72' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Aug 2020 12:57:09
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User entered 'mmHg'	System	31 Aug 2020 12:57:09
User entered empty.	System	17 Aug 2020 17:31:58

US3482064

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:39:10

US3482064

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:39:10

US3482064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:36:03

US3482064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:36:03

US3482064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

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 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:36:03

US3482064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User entered 'MRNA-1273 OR PLACEBO'	System	17 Aug 2020 15:36:03

US3482064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:36:03

US3482064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '10:56'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:36:03

US3482064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User entered '17 Aug 2020 10:56'	System	17 Aug 2020 15:36:03

US3482064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:36:03

US3482064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User entered 'ONCE'	System	17 Aug 2020 15:36:03

US3482064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User entered 'INTRAMUSCULAR'	System	17 Aug 2020 15:36:03

US3482064

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:39:45

US3482064

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:39:45

US3482064

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '10:00'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:39:45

US3482064

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User entered '17 Aug 2020 10:00'	System	17 Aug 2020 17:39:45

US3482064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:49:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:11

US3482064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	17 Aug 2020 17:40:11

US3482064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:11

US3482064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '10:05'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:11

US3482064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User entered '17 Aug 2020 10:05'	System	17 Aug 2020 17:40:11

US3482064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	17 Aug 2020 17:40:11

US3482064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:11

US3482064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:11

US3482064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User entered empty.	System	17 Aug 2020 17:40:11

US3482064

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:18

US3482064

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User entered 'I'	System	17 Aug 2020 17:40:18

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T11:37:10', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '62fc2ed1-4f3a-4d24-8a5c-fe7983c4eb76' User entered 'Yes (Y)'	System	17 Aug 2020 15:37:50
	System	17 Aug 2020 15:37:50

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T11:37:27', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '62fc2ed1-4f3a-4d24-8a5c-fe7983c4eb76' User entered '97.1'	System	17 Aug 2020 15:37:50
	System	17 Aug 2020 15:37:50

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T11:37:33', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '62fc2ed1-4f3a-4d24-8a5c-fe7983c4eb76'	System	17 Aug 2020 15:37:50
User entered 'No (N)'	System	17 Aug 2020 15:37:50

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T11:37:43', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '62fc2ed1-4f3a-4d24-8a5c-fe7983c4eb76' User entered '17 Aug 2020 11:37'	System	17 Aug 2020 15:37:50
	System	17 Aug 2020 15:37:50

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '17 Aug 2020 11:16'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '17 Aug 2020 13:46'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T18:34:07', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'cd1bb71d-55b9-4665-a084-32bf70ea8713' User entered 'Yes (Y)'	System	17 Aug 2020 22:34:37
	System	17 Aug 2020 22:34:37

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T18:34:17', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'cd1bb71d-55b9-4665-a084-32bf70ea8713' User entered '98.5'	System	17 Aug 2020 22:34:37
	System	17 Aug 2020 22:34:37

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T18:34:22', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'cd1bb71d-55b9-4665-a084-32bf70ea8713' User entered 'No (N)'	System	17 Aug 2020 22:34:37
	System	17 Aug 2020 22:34:37

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T18:34:33', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'cd1bb71d-55b9-4665-a084-32bf70ea8713' User entered '17 Aug 2020 18:34'	System	17 Aug 2020 22:34:37
	System	17 Aug 2020 22:34:37

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '17 Aug 2020 14:41'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 2'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-18T18:26:59', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '85d9997c-0ac8-4e9c-84ab-cb38b36d5b10' User entered 'Yes (Y)'	System	18 Aug 2020 22:27:28
	System	18 Aug 2020 22:27:28

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-18T18:27:06', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '85d9997c-0ac8-4e9c-84ab-cb38b36d5b10' User entered '98.1'	System	18 Aug 2020 22:27:28
	System	18 Aug 2020 22:27:28

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-18T18:27:11', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '85d9997c-0ac8-4e9c-84ab-cb38b36d5b10' User entered 'No (N)'	System	18 Aug 2020 22:27:28
	System	18 Aug 2020 22:27:28

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-18T18:27:24', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '85d9997c-0ac8-4e9c-84ab-cb38b36d5b10' User entered '18 Aug 2020 18:27'	System	18 Aug 2020 22:27:28
	System	18 Aug 2020 22:27:28

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 3'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-19T18:20:43', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '99797abc-e711-49b8-8e9b-b10834cb01ea' User entered 'Yes (Y)'	System	19 Aug 2020 22:21:10
	System	19 Aug 2020 22:21:10

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-19T18:20:55', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '99797abc-e711-49b8-8e9b-b10834cb01ea' User entered '97.8'	System	19 Aug 2020 22:21:10
	System	19 Aug 2020 22:21:10

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-19T18:21:01', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '99797abc-e711-49b8-8e9b-b10834cb01ea' User entered 'No (N)'	System	19 Aug 2020 22:21:10
	System	19 Aug 2020 22:21:10

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-19T18:21:08', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '99797abc-e711-49b8-8e9b-b10834cb01ea' User entered '19 Aug 2020 18:21'	System	19 Aug 2020 22:21:10
	System	19 Aug 2020 22:21:10

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 4'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-20T18:19:35', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'e3f0fc95-e883-4cb2-9d4c-019f7c92768b' User entered 'Yes (Y)'	System	20 Aug 2020 22:20:22
	System	20 Aug 2020 22:20:22

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-20T18:19:44', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'e3f0fc95-e883-4cb2-9d4c-019f7c92768b' User entered '97.6'	System	20 Aug 2020 22:20:22
	System	20 Aug 2020 22:20:22

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-20T18:19:50', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'e3f0fc95-e883-4cb2-9d4c-019f7c92768b' User entered 'No (N)'	System	20 Aug 2020 22:20:22
	System	20 Aug 2020 22:20:22

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-20T18:20:17', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'e3f0fc95-e883-4cb2-9d4c-019f7c92768b' User entered '20 Aug 2020 18:20'	System	20 Aug 2020 22:20:22
	System	20 Aug 2020 22:20:22

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 5'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-21T18:37:38', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'e7494c9f-548b-4a1d-8c5a-37ff3b738771' User entered 'Yes (Y)'	System	21 Aug 2020 22:38:00
	System	21 Aug 2020 22:38:00

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-21T18:37:45', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'e7494c9f-548b-4a1d-8c5a-37ff3b738771' User entered '97.6'	System	21 Aug 2020 22:38:00
	System	21 Aug 2020 22:38:00

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-21T18:37:49', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'e7494c9f-548b-4a1d-8c5a-37ff3b738771'	System	21 Aug 2020 22:38:00
User entered 'No (N)'	System	21 Aug 2020 22:38:00

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-21T18:37:55', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'e7494c9f-548b-4a1d-8c5a-37ff3b738771' User entered '21 Aug 2020 18:37'	System	21 Aug 2020 22:38:00
	System	21 Aug 2020 22:38:00

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 6'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-22T18:23:31', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '14feb107-806e-412f-94ad-92bc51a2b5fd' User entered 'Yes (Y)'	System	22 Aug 2020 22:24:31
	System	22 Aug 2020 22:24:31

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-22T18:24:01', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '14feb107-806e-412f-94ad-92bc51a2b5fd' User entered '97.5'	System	22 Aug 2020 22:24:31
	System	22 Aug 2020 22:24:31

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-22T18:24:06', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '14feb107-806e-412f-94ad-92bc51a2b5fd'	System	22 Aug 2020 22:24:31
User entered 'No (N)'	System	22 Aug 2020 22:24:31

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-22T18:24:29', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '14feb107-806e-412f-94ad-92bc51a2b5fd'	System	22 Aug 2020 22:24:31
User entered '22 Aug 2020 18:24'	System	22 Aug 2020 22:24:31

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 7'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-23T18:26:13', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '04b29099-3c13-4c5a-8386-b6bd81ba5545'	System	23 Aug 2020 22:26:36
User entered 'Yes (Y)'	System	23 Aug 2020 22:26:36

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-23T18:26:19', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '04b29099-3c13-4c5a-8386-b6bd81ba5545'	System	23 Aug 2020 22:26:36
User entered '97.5'	System	23 Aug 2020 22:26:36

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-23T18:26:23', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '04b29099-3c13-4c5a-8386-b6bd81ba5545'	System	23 Aug 2020 22:26:36
User entered 'No (N)'	System	23 Aug 2020 22:26:36

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-23T18:26:32', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '04b29099-3c13-4c5a-8386-b6bd81ba5545'	System	23 Aug 2020 22:26:36
User entered '23 Aug 2020 18:26'	System	23 Aug 2020 22:26:36

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T11:37:58', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '2af159da-2715-4718-8ba9-be70834faab7' User entered 'None (1)'	System	17 Aug 2020 15:38:31
	System	17 Aug 2020 15:38:31

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T11:38:04', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '2af159da-2715-4718-8ba9-be70834faab7' User entered 'No (N)'	System	17 Aug 2020 15:38:31
	System	17 Aug 2020 15:38:31

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T11:38:17', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '2af159da-2715-4718-8ba9-be70834faab7' User entered 'No (N)'	System	17 Aug 2020 15:38:31
	System	17 Aug 2020 15:38:31

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T11:38:22', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '2af159da-2715-4718-8ba9-be70834faab7'	System	17 Aug 2020 15:38:31
User entered 'None (1)'	System	17 Aug 2020 15:38:31

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T11:38:28', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '2af159da-2715-4718-8ba9-be70834faab7' User entered '17 Aug 2020 11:38'	System	17 Aug 2020 15:38:31
	System	17 Aug 2020 15:38:31

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '17 Aug 2020 11:16'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '17 Aug 2020 13:46'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T18:35:42', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'e4c6db1e-18a3-44ae-ba66-d0d29939907f' User entered 'Does not interfere with activity (2)'	System	17 Aug 2020 22:37:05
	System	17 Aug 2020 22:37:05

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T18:35:55', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'e4c6db1e-18a3-44ae-ba66-d0d29939907f' User entered 'Yes (Y)'	System	17 Aug 2020 22:37:05
	System	17 Aug 2020 22:37:05

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T18:36:22', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'e4c6db1e-18a3-44ae-ba66-d0d29939907f' User entered '2'	System	17 Aug 2020 22:37:05
	System	17 Aug 2020 22:37:05

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T18:36:32', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'e4c6db1e-18a3-44ae-ba66-d0d29939907f' User entered 'No (N)'	System	17 Aug 2020 22:37:05
	System	17 Aug 2020 22:37:05

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T18:36:41', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'e4c6db1e-18a3-44ae-ba66-d0d29939907f' User entered 'None (1)'	System	17 Aug 2020 22:37:05
	System	17 Aug 2020 22:37:05

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T18:37:03', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'e4c6db1e-18a3-44ae-ba66-d0d29939907f' User entered '17 Aug 2020 18:37'	System	17 Aug 2020 22:37:05
	System	17 Aug 2020 22:37:05

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '17 Aug 2020 14:41'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 2'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-18T18:27:52', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '93f1c790-dfa2-41b6-b7c5-51c980effc6d'	System	18 Aug 2020 22:31:45
User entered 'Does not interfere with activity (2)'	System	18 Aug 2020 22:31:45

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-18T18:28:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '93f1c790-dfa2-41b6-b7c5-51c980effc6d' User entered 'Yes (Y)'	System	18 Aug 2020 22:31:45
	System	18 Aug 2020 22:31:45

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:45

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-18T18:28:11', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '93f1c790-dfa2-41b6-b7c5-51c980effc6d' User entered '2'	System	18 Aug 2020 22:31:45
	System	18 Aug 2020 22:31:45

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-18T18:28:18', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '93f1c790-dfa2-41b6-b7c5-51c980effc6d' User entered 'Yes (Y)'	System	18 Aug 2020 22:31:45
	System	18 Aug 2020 22:31:45

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:45

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-18T18:30:06', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '93f1c790-dfa2-41b6-b7c5-51c980effc6d' User entered '30'	System	18 Aug 2020 22:31:45
	System	18 Aug 2020 22:31:45

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-18T18:31:15', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '93f1c790-dfa2-41b6-b7c5-51c980effc6d' User entered 'None (1)'	System	18 Aug 2020 22:31:45
	System	18 Aug 2020 22:31:45

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-18T18:31:44', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '93f1c790-dfa2-41b6-b7c5-51c980effc6d' User entered '18 Aug 2020 18:31'	System	18 Aug 2020 22:31:45
	System	18 Aug 2020 22:31:45

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 3'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-19T18:21:22', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'fe5154d3-63e8-4db8-bc03-3ba7e2ddf97a' User entered 'None (1)'	System	19 Aug 2020 22:22:46
	System	19 Aug 2020 22:22:46

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-19T18:21:56', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'fe5154d3-63e8-4db8-bc03-3ba7e2ddf97a' User entered 'No (N)'	System	19 Aug 2020 22:22:46
	System	19 Aug 2020 22:22:46

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-19T18:22:04', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'fe5154d3-63e8-4db8-bc03-3ba7e2ddf97a' User entered 'Yes (Y)'	System	19 Aug 2020 22:22:46
	System	19 Aug 2020 22:22:46

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:45

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-19T18:22:18', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'fe5154d3-63e8-4db8-bc03-3ba7e2ddf97a' User entered '20'	System	19 Aug 2020 22:22:46
	System	19 Aug 2020 22:22:46

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-19T18:22:28', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'fe5154d3-63e8-4db8-bc03-3ba7e2ddf97a' User entered 'None (1)'	System	19 Aug 2020 22:22:46
	System	19 Aug 2020 22:22:46

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-19T18:22:44', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'fe5154d3-63e8-4db8-bc03-3ba7e2ddf97a' User entered '19 Aug 2020 18:22'	System	19 Aug 2020 22:22:46
	System	19 Aug 2020 22:22:46

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 4'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-20T18:20:28', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '8dacbf8-33cd-40ab-94e0-0f6fcfc351f9'	System	20 Aug 2020 22:21:38
User entered 'None (1)'	System	20 Aug 2020 22:21:38

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-20T18:20:37', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '8dacbf8-33cd-40ab-94e0-0f6fcfc351f9'	System	20 Aug 2020 22:21:38
User entered 'No (N)'	System	20 Aug 2020 22:21:38

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-20T18:20:49', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '8dacfb8-33cd-40ab-94e0-0f6fcfc351f9'	System	20 Aug 2020 22:21:38
User entered 'No (N)'	System	20 Aug 2020 22:21:38

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-20T18:20:58', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '8dacbf8-33cd-40ab-94e0-0f6fcfc351f9'	System	20 Aug 2020 22:21:38
User entered 'None (1)'	System	20 Aug 2020 22:21:38

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-20T18:21:34', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '8dacbf8-33cd-40ab-94e0-0f6fcfc351f9'	System	20 Aug 2020 22:21:38
User entered '20 Aug 2020 18:21'	System	20 Aug 2020 22:21:38

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 5'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-21T18:38:03', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'bccd1dd6-9118-42d9-9b21-b8ad6e88cf8b' User entered 'None (1)'	System	21 Aug 2020 22:38:28
	System	21 Aug 2020 22:38:28

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-21T18:38:08', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'bccd1dd6-9118-42d9-9b21-b8ad6e88cf8b' User entered 'No (N)'	System	21 Aug 2020 22:38:28
	System	21 Aug 2020 22:38:28

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-21T18:38:13', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'bccd1dd6-9118-42d9-9b21-b8ad6e88cf8b' User entered 'No (N)'	System	21 Aug 2020 22:38:28
	System	21 Aug 2020 22:38:28

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-21T18:38:17', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'bccd1dd6-9118-42d9-9b21-b8ad6e88cf8b' User entered 'None (1)'	System	21 Aug 2020 22:38:28
	System	21 Aug 2020 22:38:28

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-21T18:38:27', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'bccd1dd6-9118-42d9-9b21-b8ad6e88cf8b' User entered '21 Aug 2020 18:38'	System	21 Aug 2020 22:38:28
	System	21 Aug 2020 22:38:28

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 6'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-22T18:24:35', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'f2d9b111-e869-450e-9cea-b6b4405a059b' User entered 'None (1)'	System	22 Aug 2020 22:24:56
	System	22 Aug 2020 22:24:56

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-22T18:24:39', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'f2d9b111-e869-450e-9cea-b6b4405a059b' User entered 'No (N)'	System	22 Aug 2020 22:24:56
	System	22 Aug 2020 22:24:56

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-22T18:24:42', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'f2d9b111-e869-450e-9cea-b6b4405a059b' User entered 'No (N)'	System	22 Aug 2020 22:24:56
	System	22 Aug 2020 22:24:56

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-22T18:24:46', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'f2d9b111-e869-450e-9cea-b6b4405a059b'	System	22 Aug 2020 22:24:56
User entered 'None (1)'	System	22 Aug 2020 22:24:56

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-22T18:24:53', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'f2d9b111-e869-450e-9cea-b6b4405a059b' User entered '22 Aug 2020 18:24'	System	22 Aug 2020 22:24:56
	System	22 Aug 2020 22:24:56

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 7'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-23T18:26:38', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'ec05da72-463f-4d21-988d-5edf0b7ca38b'	System	23 Aug 2020 22:27:14
User entered 'None (1)'	System	23 Aug 2020 22:27:14

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-23T18:26:43', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'ec05da72-463f-4d21-988d-5edf0b7ca38b' User entered 'No (N)'	System	23 Aug 2020 22:27:14
	System	23 Aug 2020 22:27:14

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-23T18:26:47', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'ec05da72-463f-4d21-988d-5edf0b7ca38b' User entered 'No (N)'	System	23 Aug 2020 22:27:14
	System	23 Aug 2020 22:27:14

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-23T18:26:51', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'ec05da72-463f-4d21-988d-5edf0b7ca38b'	System	23 Aug 2020 22:27:14
User entered 'None (1)'	System	23 Aug 2020 22:27:14

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-23T18:27:12', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'ec05da72-463f-4d21-988d-5edf0b7ca38b' User entered '23 Aug 2020 18:27'	System	23 Aug 2020 22:27:14
	System	23 Aug 2020 22:27:14

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T11:38:42', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '1706fb73-a8d6-4cd4-a6fa-29b4e0c30589' User entered 'None (0)'	System	17 Aug 2020 15:39:21
	System	17 Aug 2020 15:39:21

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T11:38:45', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '1706fb73-a8d6-4cd4-a6fa-29b4e0c30589' User entered 'None (0)'	System	17 Aug 2020 15:39:21
	System	17 Aug 2020 15:39:21

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T11:38:49', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '1706fb73-a8d6-4cd4-a6fa-29b4e0c30589' User entered 'None (0)'	System	17 Aug 2020 15:39:21
	System	17 Aug 2020 15:39:21

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T11:38:55', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '1706fb73-a8d6-4cd4-a6fa-29b4e0c30589' User entered 'None (0)'	System	17 Aug 2020 15:39:21
	System	17 Aug 2020 15:39:21

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T11:38:58', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '1706fb73-a8d6-4cd4-a6fa-29b4e0c30589' User entered 'None (0)'	System	17 Aug 2020 15:39:21
	System	17 Aug 2020 15:39:21

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T11:39:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '1706fb73-a8d6-4cd4-a6fa-29b4e0c30589' User entered 'None (0)'	System	17 Aug 2020 15:39:21
	System	17 Aug 2020 15:39:21

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T11:39:11', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '1706fb73-a8d6-4cd4-a6fa-29b4e0c30589' User entered 'No (N)'	System	17 Aug 2020 15:39:21
	System	17 Aug 2020 15:39:21

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T11:39:17', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '1706fb73-a8d6-4cd4-a6fa-29b4e0c30589'	System	17 Aug 2020 15:39:21
User entered '17 Aug 2020 11:39'	System	17 Aug 2020 15:39:21

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '17 Aug 2020 11:16'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '17 Aug 2020 13:46'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T18:37:13', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '2407d2af-9eef-4db3-804f-ea971d060a3b' User entered 'None (0)'	System	17 Aug 2020 22:38:04
	System	17 Aug 2020 22:38:04

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T18:37:21', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '2407d2af-9eef-4db3-804f-ea971d060a3b' User entered 'None (0)'	System	17 Aug 2020 22:38:04
	System	17 Aug 2020 22:38:04

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T18:37:25', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '2407d2af-9eef-4db3-804f-ea971d060a3b' User entered 'None (0)'	System	17 Aug 2020 22:38:04
	System	17 Aug 2020 22:38:04

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T18:37:30', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '2407d2af-9eef-4db3-804f-ea971d060a3b' User entered 'None (0)'	System	17 Aug 2020 22:38:04
	System	17 Aug 2020 22:38:04

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T18:37:34', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '2407d2af-9eef-4db3-804f-ea971d060a3b' User entered 'None (0)'	System	17 Aug 2020 22:38:04
	System	17 Aug 2020 22:38:04

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T18:37:36', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '2407d2af-9eef-4db3-804f-ea971d060a3b' User entered 'None (0)'	System	17 Aug 2020 22:38:04
	System	17 Aug 2020 22:38:04

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T18:37:46', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '2407d2af-9eef-4db3-804f-ea971d060a3b'	System	17 Aug 2020 22:38:04
User entered 'No (N)'	System	17 Aug 2020 22:38:04

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-17T18:38:02', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '2407d2af-9eef-4db3-804f-ea971d060a3b'	System	17 Aug 2020 22:38:04
User entered '17 Aug 2020 18:38'	System	17 Aug 2020 22:38:04

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '17 Aug 2020 14:41'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 2'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-18T18:32:49', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '8387f0c6-d0d3-4d7b-ae0b-779a601d879a' User entered 'None (0)'	System	18 Aug 2020 22:34:12
	System	18 Aug 2020 22:34:12

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-18T18:32:47', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '8387f0c6-d0d3-4d7b-ae0b-779a601d879a' User entered 'None (0)'	System	18 Aug 2020 22:34:12
	System	18 Aug 2020 22:34:12

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-18T18:33:06', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '8387f0c6-d0d3-4d7b-ae0b-779a601d879a' User entered 'None (0)'	System	18 Aug 2020 22:34:12
	System	18 Aug 2020 22:34:12

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-18T18:33:11', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '8387f0c6-d0d3-4d7b-ae0b-779a601d879a' User entered 'None (0)'	System	18 Aug 2020 22:34:12
	System	18 Aug 2020 22:34:12

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-18T18:33:15', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '8387f0c6-d0d3-4d7b-ae0b-779a601d879a' User entered 'None (0)'	System	18 Aug 2020 22:34:12
	System	18 Aug 2020 22:34:12

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-18T18:33:18', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '8387f0c6-d0d3-4d7b-ae0b-779a601d879a' User entered 'None (0)'	System	18 Aug 2020 22:34:12
	System	18 Aug 2020 22:34:12

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-18T18:33:22', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '8387f0c6-d0d3-4d7b-ae0b-779a601d879a' User entered 'No (N)'	System	18 Aug 2020 22:34:12
	System	18 Aug 2020 22:34:12

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-18T18:34:10', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '8387f0c6-d0d3-4d7b-ae0b-779a601d879a' User entered '18 Aug 2020 18:34'	System	18 Aug 2020 22:34:12
	System	18 Aug 2020 22:34:12

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 3'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-19T18:22:52', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'f01a3334-c2a1-4c26-ab05-6c262903c051' User entered 'None (0)'	System	19 Aug 2020 22:23:45
	System	19 Aug 2020 22:23:45

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-19T18:22:56', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'f01a3334-c2a1-4c26-ab05-6c262903c051' User entered 'None (0)'	System	19 Aug 2020 22:23:45
	System	19 Aug 2020 22:23:45

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-19T18:23:02', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'f01a3334-c2a1-4c26-ab05-6c262903c051' User entered 'None (0)'	System	19 Aug 2020 22:23:45
	System	19 Aug 2020 22:23:45

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-19T18:23:06', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'f01a3334-c2a1-4c26-ab05-6c262903c051' User entered 'None (0)'	System	19 Aug 2020 22:23:45
	System	19 Aug 2020 22:23:45

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-19T18:23:09', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'f01a3334-c2a1-4c26-ab05-6c262903c051' User entered 'None (0)'	System	19 Aug 2020 22:23:45
	System	19 Aug 2020 22:23:45

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-19T18:23:13', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'f01a3334-c2a1-4c26-ab05-6c262903c051' User entered 'None (0)'	System	19 Aug 2020 22:23:45
	System	19 Aug 2020 22:23:45

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-19T18:23:30', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'f01a3334-c2a1-4c26-ab05-6c262903c051' User entered 'No (N)'	System	19 Aug 2020 22:23:45
	System	19 Aug 2020 22:23:45

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-19T18:23:42', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'f01a3334-c2a1-4c26-ab05-6c262903c051' User entered '19 Aug 2020 18:23'	System	19 Aug 2020 22:23:45
	System	19 Aug 2020 22:23:45

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 4'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-20T18:22:18', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'df1395cf-595b-45e7-8736-767c0a494f1e' User entered 'None (0)'	System	20 Aug 2020 22:23:37
	System	20 Aug 2020 22:23:37

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-20T18:22:31', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'df1395cf-595b-45e7-8736-767c0a494f1e' User entered 'None (0)'	System	20 Aug 2020 22:23:37
	System	20 Aug 2020 22:23:37

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-20T18:22:42', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'df1395cf-595b-45e7-8736-767c0a494f1e' User entered 'None (0)'	System	20 Aug 2020 22:23:37
	System	20 Aug 2020 22:23:37

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-20T18:22:47', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'df1395cf-595b-45e7-8736-767c0a494f1e' User entered 'None (0)'	System	20 Aug 2020 22:23:37
	System	20 Aug 2020 22:23:37

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-20T18:22:50', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'df1395cf-595b-45e7-8736-767c0a494f1e' User entered 'None (0)'	System	20 Aug 2020 22:23:37
	System	20 Aug 2020 22:23:37

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-20T18:22:58', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'df1395cf-595b-45e7-8736-767c0a494f1e' User entered 'None (0)'	System	20 Aug 2020 22:23:37
	System	20 Aug 2020 22:23:37

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-20T18:23:06', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'df1395cf-595b-45e7-8736-767c0a494f1e' User entered 'No (N)'	System	20 Aug 2020 22:23:37
	System	20 Aug 2020 22:23:37

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-20T18:23:34', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'df1395cf-595b-45e7-8736-767c0a494f1e' User entered '20 Aug 2020 18:23'	System	20 Aug 2020 22:23:37
	System	20 Aug 2020 22:23:37

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 5'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-21T18:38:37', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '34336c5a-448f-443e-b791-f57cafa4dd53' User entered 'None (0)'	System	21 Aug 2020 22:39:29
	System	21 Aug 2020 22:39:29

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-21T18:38:41', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '34336c5a-448f-443e-b791-f57cafa4dd53' User entered 'None (0)'	System	21 Aug 2020 22:39:29
	System	21 Aug 2020 22:39:29

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-21T18:38:45', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '34336c5a-448f-443e-b791-f57cafa4dd53' User entered 'None (0)'	System	21 Aug 2020 22:39:29
	System	21 Aug 2020 22:39:29

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-21T18:38:48', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '34336c5a-448f-443e-b791-f57cafa4dd53' User entered 'None (0)'	System	21 Aug 2020 22:39:29
	System	21 Aug 2020 22:39:29

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-21T18:38:52', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '34336c5a-448f-443e-b791-f57cafa4dd53' User entered 'None (0)'	System	21 Aug 2020 22:39:29
	System	21 Aug 2020 22:39:29

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-21T18:38:56', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '34336c5a-448f-443e-b791-f57cafa4dd53' User entered 'None (0)'	System	21 Aug 2020 22:39:29
	System	21 Aug 2020 22:39:29

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-21T18:39:01', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '34336c5a-448f-443e-b791-f57cafa4dd53'	System	21 Aug 2020 22:39:29
User entered 'No (N)'	System	21 Aug 2020 22:39:29

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-21T18:39:27', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '34336c5a-448f-443e-b791-f57cafa4dd53' User entered '21 Aug 2020 18:39'	System	21 Aug 2020 22:39:29
	System	21 Aug 2020 22:39:29

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 6'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-22T18:24:58', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '48daf989-fa1b-4b72-83b4-79527e9c5ec4' User entered 'None (0)'	System	22 Aug 2020 22:25:40
	System	22 Aug 2020 22:25:40

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-22T18:25:02', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '48daf989-fa1b-4b72-83b4-79527e9c5ec4' User entered 'None (0)'	System	22 Aug 2020 22:25:40
	System	22 Aug 2020 22:25:40

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-22T18:25:05', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '48daf989-fa1b-4b72-83b4-79527e9c5ec4' User entered 'None (0)'	System	22 Aug 2020 22:25:40
	System	22 Aug 2020 22:25:40

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-22T18:25:08', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '48daf989-fa1b-4b72-83b4-79527e9c5ec4' User entered 'None (0)'	System	22 Aug 2020 22:25:40
	System	22 Aug 2020 22:25:40

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-22T18:25:11', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '48daf989-fa1b-4b72-83b4-79527e9c5ec4' User entered 'None (0)'	System	22 Aug 2020 22:25:40
	System	22 Aug 2020 22:25:40

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-22T18:25:14', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '48daf989-fa1b-4b72-83b4-79527e9c5ec4' User entered 'None (0)'	System	22 Aug 2020 22:25:40
	System	22 Aug 2020 22:25:40

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-22T18:25:18', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '48daf989-fa1b-4b72-83b4-79527e9c5ec4' User entered 'No (N)'	System	22 Aug 2020 22:25:40
	System	22 Aug 2020 22:25:40

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-22T18:25:39', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '48daf989-fa1b-4b72-83b4-79527e9c5ec4' User entered '22 Aug 2020 18:25'	System	22 Aug 2020 22:25:40
	System	22 Aug 2020 22:25:40

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 7'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-23T18:27:19', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '2d5f7177-e69e-4009-822d-7f8683cd8f17' User entered 'None (0)'	System	23 Aug 2020 22:28:07
	System	23 Aug 2020 22:28:07

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-23T18:27:23', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '2d5f7177-e69e-4009-822d-7f8683cd8f17' User entered 'None (0)'	System	23 Aug 2020 22:28:07
	System	23 Aug 2020 22:28:07

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-23T18:27:26', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '2d5f7177-e69e-4009-822d-7f8683cd8f17' User entered 'None (0)'	System	23 Aug 2020 22:28:07
	System	23 Aug 2020 22:28:07

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-23T18:27:30', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '2d5f7177-e69e-4009-822d-7f8683cd8f17' User entered 'None (0)'	System	23 Aug 2020 22:28:07
	System	23 Aug 2020 22:28:07

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-23T18:27:35', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '2d5f7177-e69e-4009-822d-7f8683cd8f17' User entered 'None (0)'	System	23 Aug 2020 22:28:07
	System	23 Aug 2020 22:28:07

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-23T18:27:39', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '2d5f7177-e69e-4009-822d-7f8683cd8f17' User entered 'None (0)'	System	23 Aug 2020 22:28:07
	System	23 Aug 2020 22:28:07

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-23T18:27:47', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '2d5f7177-e69e-4009-822d-7f8683cd8f17' User entered 'No (N)'	System	23 Aug 2020 22:28:07
	System	23 Aug 2020 22:28:07

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-08-23T18:28:04', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '2d5f7177-e69e-4009-822d-7f8683cd8f17' User entered '23 Aug 2020 18:28'	System	23 Aug 2020 22:28:07
	System	23 Aug 2020 22:28:07

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 15:36:03

US3482064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 16:21:25

US3482064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 16:21:25

US3482064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 16:21:25

US3482064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 16:21:25

US3482064

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 16:21:33

US3482064

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User entered 'I'	System	26 Aug 2020 16:21:33

US3482064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:38:12

US3482064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:38:12

US3482064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:38:12

US3482064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:38:12

US3482064

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:38:21

US3482064

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:08:59
User entered 'I'	System	31 Aug 2020 21:38:21

US3482064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:08:16
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:45:48

US3482064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:08:16
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:45:48

US3482064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:08:16
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:45:48

US3482064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:08:16
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:45:48

US3482064

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:08:16
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:45:55

US3482064

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:08:16
User entered 'I'	System	08 Sep 2020 18:45:55

US3482064

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:48:40

US3482064

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:48:40

US3482064

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

[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 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:48:40

US3482064

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered 'VISIT2'	System	14 Sep 2020 17:48:40

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '08:45'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered '14 Sep 2020 08:45'	System	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '73'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered 'bpm'	System	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '16'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered 'breaths/min'	System	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '129'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered 'mmHg'	System	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '60'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered 'mmHg'	System	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered empty.	System	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered empty.	System	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered empty.	System	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered empty.	System	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered empty.	System	14 Sep 2020 17:54:52

US3482064

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:48:59

US3482064

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:48:59

US3482064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:49:11

US3482064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:49:11

US3482064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

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 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:49:11

US3482064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered empty.	System	14 Sep 2020 17:49:11

US3482064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:49:11

US3482064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:49:11

US3482064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered empty.	System	14 Sep 2020 17:49:11

US3482064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:49:11

US3482064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered empty.	System	14 Sep 2020 17:49:11

US3482064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered empty.	System	14 Sep 2020 17:49:11

US3482064

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:49:32

US3482064

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:49:32

US3482064

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '09:05' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:50:30
User entered '09:10'	(b) (4), (b) (6)	14 Sep 2020 17:49:32

US3482064

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered '14 Sep 2020 09:05'	System	14 Sep 2020 17:50:30
User entered '14 Sep 2020 09:10'	System	14 Sep 2020 17:49:32

US3482064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:49:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:49:51

US3482064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	14 Sep 2020 17:49:51

US3482064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:49:51

US3482064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '09:05' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:50:39
User entered '09:10'	(b) (4), (b) (6)	14 Sep 2020 17:49:51

US3482064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered '14 Sep 2020 09:05'	System	14 Sep 2020 17:50:39
User entered '14 Sep 2020 09:10'	System	14 Sep 2020 17:49:51

US3482064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	14 Sep 2020 17:49:51

US3482064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:49:51

US3482064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:49:51

US3482064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered empty.	System	14 Sep 2020 17:49:51

US3482064

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:49:58

US3482064

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered '1'	System	14 Sep 2020 17:49:58

US3482064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:48:09

US3482064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:48:09

US3482064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:48:09

US3482064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:48:09

US3482064

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:48:19

US3482064

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered 'I'	System	13 Oct 2020 12:48:19

US3482064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:48:47

US3482064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:48:47

US3482064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:48:47

US3482064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:48:47

US3482064

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:48:57

US3482064

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered 'I'	System	13 Oct 2020 12:48:57

US3482064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:49:05

US3482064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:49:05

US3482064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:49:05

US3482064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:49:05

US3482064

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:49:12

US3482064

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered 'I'	System	13 Oct 2020 12:49:12

US3482064

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:49:31

US3482064

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:49:31

US3482064

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

[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 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:49:31

US3482064

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered 'VISIT3'	System	13 Oct 2020 12:49:31

US3482064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:49:38

US3482064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:49:38

US3482064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:49:38

US3482064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered empty.	System	13 Oct 2020 12:49:38

US3482064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:49:38

US3482064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:49:38

US3482064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:49:38

US3482064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:49:38

US3482064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered empty.	System	13 Oct 2020 12:49:38

US3482064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:49:38

US3482064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered empty.	System	13 Oct 2020 12:49:38

US3482064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:49:38

US3482064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered empty.	System	13 Oct 2020 12:49:38

US3482064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:49:38

US3482064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered empty.	System	13 Oct 2020 12:49:38

US3482064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42

US3482064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42

US3482064

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:49:43

US3482064

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:49:43

US3482064

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:50:04

US3482064

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:50:04

US3482064

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered '08:35'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:50:04

US3482064

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered '12 Oct 2020 08:35'	System	13 Oct 2020 12:50:04

US3482064

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:17:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 12:50:13

US3482064

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered '1'	System	13 Oct 2020 12:50:13

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 64'	System	17 Aug 2020 15:36:03

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-10-20T18:17:39', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'b453cc82-0126-4da1-a7c1-403bcb9a6449' User entered 'No (N)'	System	20 Oct 2020 22:20:31
	System	20 Oct 2020 22:20:31

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

Have you been exposed to someone with 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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-10-20T18:17:45', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'b453cc82-0126-4da1-a7c1-403bcb9a6449' User entered 'No (N)'	System	20 Oct 2020 22:20:31
	System	20 Oct 2020 22:20:31

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-10-20T18:20:27', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'b453cc82-0126-4da1-a7c1-403bcb9a6449' User entered '20 Oct 2020 18:20:27'	System	20 Oct 2020 22:20:31
	System	20 Oct 2020 22:20:31

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 15:36:03

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 71'	System	17 Aug 2020 15:36:03

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-10-26T18:36:39', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '6476fe73-b1b4-49ae-b5c6-866a65e9efbc' User entered 'No (N)'	System	26 Oct 2020 22:37:09
	System	26 Oct 2020 22:37:09

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

Have you been exposed to someone with 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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-10-26T18:36:48', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '6476fe73-b1b4-49ae-b5c6-866a65e9efbc'	System	26 Oct 2020 22:37:09
User entered 'No (N)'	System	26 Oct 2020 22:37:09

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-10-26T18:37:05', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '6476fe73-b1b4-49ae-b5c6-866a65e9efbc' User entered '26 Oct 2020 18:37:05'	System	26 Oct 2020 22:37:09
	System	26 Oct 2020 22:37:09

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 15:36:03

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 78'	System	17 Aug 2020 15:36:03

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-11-02T22:12:04', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '95f4bc69-a7e4-454e-a440-5c0b44e35578' User entered 'No (N)'	System	03 Nov 2020 03:12:41
	System	03 Nov 2020 03:12:41

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

Have you been exposed to someone with 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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-11-02T22:12:13', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '95f4bc69-a7e4-454e-a440-5c0b44e35578'	System	03 Nov 2020 03:12:41
User entered 'No (N)'	System	03 Nov 2020 03:12:41

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-11-02T22:12:37', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '95f4bc69-a7e4-454e-a440-5c0b44e35578' User entered '02 Nov 2020 22:12:37'	System	03 Nov 2020 03:12:41
	System	03 Nov 2020 03:12:41

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 15:36:03

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered 'Day 92'	System	17 Aug 2020 15:36:03

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-11-15T21:23:59', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '91ee5f71-c824-4898-a3b3-33e5c5e5ddf5'	System	16 Nov 2020 02:24:45
User entered 'No (N)'	System	16 Nov 2020 02:24:45

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

Have you been exposed to someone with 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 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-11-15T21:24:10', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '91ee5f71-c824-4898-a3b3-33e5c5e5ddf5'	System	16 Nov 2020 02:24:45
User entered 'No (N)'	System	16 Nov 2020 02:24:45

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-11-15T21:24:42', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '91ee5f71-c824-4898-a3b3-33e5c5e5ddf5' User entered '15 Nov 2020 21:24:42'	System	16 Nov 2020 02:24:45
	System	16 Nov 2020 02:24:45

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 15:36:03

US3482064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:04:31
Data entry locked.	System	17 Aug 2020 15:36:03
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 15:36:03

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-11-19T13:21:17', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '428553f6-ad5c-4afe-ba11-258534f28716'	System	19 Nov 2020 18:22:07
User entered 'No (N)'	System	19 Nov 2020 18:22:07

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-11-19T13:21:30', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '428553f6-ad5c-4afe-ba11-258534f28716'	System	19 Nov 2020 18:22:07
User entered 'No (N)'	System	19 Nov 2020 18:22:07

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-11-19T13:22:02', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '428553f6-ad5c-4afe-ba11-258534f28716' User entered '19 Nov 2020 13:22:02'	System	19 Nov 2020 18:22:07
	System	19 Nov 2020 18:22:07

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-11-25T16:51:03', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '3c62cf14-9525-4106-a79e-4c4b9108550b' User entered 'No (N)'	System	25 Nov 2020 21:51:33
	System	25 Nov 2020 21:51:33

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-11-25T16:51:13', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '3c62cf14-9525-4106-a79e-4c4b9108550b' User entered 'No (N)'	System	25 Nov 2020 21:51:33

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-11-25T16:51:30', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '3c62cf14-9525-4106-a79e-4c4b9108550b' User entered '25 Nov 2020 16:51:30'	System	25 Nov 2020 21:51:33
	System	25 Nov 2020 21:51:33

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-12-02T17:14:39', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'f0f7360b-b489-4472-a5c3-78481bc520ff' User entered 'No (N)'	System	02 Dec 2020 22:15:16
	System	02 Dec 2020 22:15:16

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-12-02T17:14:48', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'f0f7360b-b489-4472-a5c3-78481bc520ff' User entered 'No (N)'	System	02 Dec 2020 22:15:16
	System	02 Dec 2020 22:15:16

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-12-02T17:15:13', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'f0f7360b-b489-4472-a5c3-78481bc520ff' User entered '02 Dec 2020 17:15:13'	System	02 Dec 2020 22:15:16
	System	02 Dec 2020 22:15:16

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-12-09T08:25:25', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '8e9780d2-a8fd-40f9-abc4-c7b128c9440f' User entered 'No (N)'	System	09 Dec 2020 13:26:17
	System	09 Dec 2020 13:26:17

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-12-09T08:25:49', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '8e9780d2-a8fd-40f9-abc4-c7b128c9440f' User entered 'No (N)'	System	09 Dec 2020 13:26:17
	System	09 Dec 2020 13:26:17

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-12-09T08:26:15', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '8e9780d2-a8fd-40f9-abc4-c7b128c9440f' User entered '09 Dec 2020 08:26:15'	System	09 Dec 2020 13:26:17
	System	09 Dec 2020 13:26:17

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-12-16T15:41:57', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'dd81d962-3201-4073-9073-395d93d18de4'	System	16 Dec 2020 20:42:23
User entered 'No (N)'	System	16 Dec 2020 20:42:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-12-16T15:42:03', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'dd81d962-3201-4073-9073-395d93d18de4'	System	16 Dec 2020 20:42:23
User entered 'No (N)'	System	16 Dec 2020 20:42:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-12-16T15:42:19', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'dd81d962-3201-4073-9073-395d93d18de4' User entered '16 Dec 2020 15:42:19'	System	16 Dec 2020 20:42:23
	System	16 Dec 2020 20:42:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-12-23T00:02:22', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'b8243743-68b5-4185-ac8f-c4640c64b4ff'	System	23 Dec 2020 05:03:10
User entered 'No (N)'	System	23 Dec 2020 05:03:10

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-12-23T00:02:39', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'b8243743-68b5-4185-ac8f-c4640c64b4ff'	System	23 Dec 2020 05:03:10
User entered 'No (N)'	System	23 Dec 2020 05:03:10

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-12-23T00:03:01', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'b8243743-68b5-4185-ac8f-c4640c64b4ff' User entered '23 Dec 2020 00:03:01'	System	23 Dec 2020 05:03:10
	System	23 Dec 2020 05:03:10

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-12-30T13:16:59', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'd0766f17-60f2-4b2f-8a70-d30dd69d0e0f' User entered 'No (N)'	System	30 Dec 2020 18:17:33
	System	30 Dec 2020 18:17:33

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-12-30T13:17:09', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'd0766f17-60f2-4b2f-8a70-d30dd69d0e0f'	System	30 Dec 2020 18:17:33
User entered 'No (N)'	System	30 Dec 2020 18:17:33

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2020-12-30T13:17:31', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'd0766f17-60f2-4b2f-8a70-d30dd69d0e0f' User entered '30 Dec 2020 13:17:31'	System	30 Dec 2020 18:17:33
	System	30 Dec 2020 18:17:33

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-01-06T16:30:47', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '6696ecef-b02a-4603-93ce-17bb1466c23f' User entered 'No (N)'	System	06 Jan 2021 21:31:19
	System	06 Jan 2021 21:31:19

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-01-06T16:30:58', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '6696ecef-b02a-4603-93ce-17bb1466c23f'	System	06 Jan 2021 21:31:19
User entered 'No (N)'	System	06 Jan 2021 21:31:19

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-01-06T16:31:15', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '6696ecef-b02a-4603-93ce-17bb1466c23f' User entered '06 Jan 2021 16:31:15'	System	06 Jan 2021 21:31:19
	System	06 Jan 2021 21:31:19

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-01-15T11:23:20', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '4a8600bf-2b79-4d15-9155-1bb6f1cdfb3b'	System	15 Jan 2021 16:24:05
User entered 'No (N)'	System	15 Jan 2021 16:24:05

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-01-15T11:23:26', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '4a8600bf-2b79-4d15-9155-1bb6f1cdfb3b'	System	15 Jan 2021 16:24:05
User entered 'No (N)'	System	15 Jan 2021 16:24:05

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-01-15T11:24:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '4a8600bf-2b79-4d15-9155-1bb6f1cdfb3b' User entered '15 Jan 2021 11:24:00'	System	15 Jan 2021 16:24:05
	System	15 Jan 2021 16:24:05

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-01-20T13:25:11', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '0333324a-d771-4f96-8830-651a52f5efd8' User entered 'Yes (Y)'	System	20 Jan 2021 18:26:54
	System	20 Jan 2021 18:26:54

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-01-20T13:25:21', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '0333324a-d771-4f96-8830-651a52f5efd8'	System	20 Jan 2021 18:26:54
User entered 'No (N)'	System	20 Jan 2021 18:26:54

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-01-20T13:25:36', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '0333324a-d771-4f96-8830-651a52f5efd8' User entered 'No (N)'	System	20 Jan 2021 18:26:54
	System	20 Jan 2021 18:26:54

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-01-20T13:26:29', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '0333324a-d771-4f96-8830-651a52f5efd8' User entered 'No (N)'	System	20 Jan 2021 18:26:54
	System	20 Jan 2021 18:26:54

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-01-20T13:26:52', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '0333324a-d771-4f96-8830-651a52f5efd8' User entered '20 Jan 2021 13:26:52'	System	20 Jan 2021 18:26:54
	System	20 Jan 2021 18:26:54

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-01-27T11:34:10', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'b17d1550-ca29-4f3c-94c4-7cabcc734e38' User entered 'No (N)'	System	27 Jan 2021 16:34:25
	System	27 Jan 2021 16:34:25

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-01-27T11:34:16', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'b17d1550-ca29-4f3c-94c4-7cabcc734e38'	System	27 Jan 2021 16:34:25
User entered 'No (N)'	System	27 Jan 2021 16:34:25

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-01-27T11:34:21', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'b17d1550-ca29-4f3c-94c4-7cabcc734e38' User entered '27 Jan 2021 11:34:21'	System	27 Jan 2021 16:34:25
	System	27 Jan 2021 16:34:25

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-02-03T17:00:36', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'c7cc1890-36ba-4796-b45c-feb1edfffa64'	System	03 Feb 2021 22:00:50
User entered 'No (N)'	System	03 Feb 2021 22:00:50

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-02-03T17:00:40', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'c7cc1890-36ba-4796-b45c-feb1edfffa64'	System	03 Feb 2021 22:00:50
User entered 'No (N)'	System	03 Feb 2021 22:00:50

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-02-03T17:00:47', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'c7cc1890-36ba-4796-b45c-feb1edfffa64'	System	03 Feb 2021 22:00:50
User entered '03 Feb 2021 17:00:47'	System	03 Feb 2021 22:00:50

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-02-10T07:59:35', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '9c8a8945-90e0-4c1e-9253-e02931460c59' User entered 'No (N)'	System	10 Feb 2021 13:00:08
	System	10 Feb 2021 13:00:08

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-02-10T07:59:42', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '9c8a8945-90e0-4c1e-9253-e02931460c59' User entered 'No (N)'	System	10 Feb 2021 13:00:08

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-02-10T08:00:02', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '9c8a8945-90e0-4c1e-9253-e02931460c59' User entered '10 Feb 2021 08:00:02'	System	10 Feb 2021 13:00:08
	System	10 Feb 2021 13:00:08

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-02-17T09:44:55', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '9236aa4a-d878-408f-83aa-d6b0c291ab77'	System	17 Feb 2021 14:45:32
User entered 'No (N)'	System	17 Feb 2021 14:45:32

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-02-17T09:45:01', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '9236aa4a-d878-408f-83aa-d6b0c291ab77'	System	17 Feb 2021 14:45:32
User entered 'No (N)'	System	17 Feb 2021 14:45:32

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-02-17T09:45:29', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '9236aa4a-d878-408f-83aa-d6b0c291ab77'	System	17 Feb 2021 14:45:32
User entered '17 Feb 2021 09:45:29'	System	17 Feb 2021 14:45:32

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-02-24T21:41:18', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'ebbdee54-44aa-41bd-9db8-2e4cd99f3e2d' User entered 'No (N)'	System	25 Feb 2021 02:49:13
	System	25 Feb 2021 02:49:13

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-02-24T21:41:22', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'ebbdee54-44aa-41bd-9db8-2e4cd99f3e2d'	System	25 Feb 2021 02:49:13
User entered 'No (N)'	System	25 Feb 2021 02:49:13

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-02-24T21:41:55', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'ebbdee54-44aa-41bd-9db8-2e4cd99f3e2d' User entered '24 Feb 2021 21:41:55'	System	25 Feb 2021 02:49:13

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-03-03T00:37:16', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '96d9127c-3e99-4a74-8aab-f54cfd6332e9'	System	03 Mar 2021 05:37:46
User entered 'No (N)'	System	03 Mar 2021 05:37:46

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-03-03T00:37:26', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '96d9127c-3e99-4a74-8aab-f54cfd6332e9'	System	03 Mar 2021 05:37:46
User entered 'No (N)'	System	03 Mar 2021 05:37:46

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-03-03T00:37:44', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '96d9127c-3e99-4a74-8aab-f54cfd6332e9' User entered '03 Mar 2021 00:37:44'	System	03 Mar 2021 05:37:46
	System	03 Mar 2021 05:37:46

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-03-10T12:02:21', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '7b1c2ea9-8f49-454f-a898-2198cc2ec0c2'	System	10 Mar 2021 17:09:55
User entered 'No (N)'	System	10 Mar 2021 17:09:55

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-03-10T12:02:25', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '7b1c2ea9-8f49-454f-a898-2198cc2ec0c2'	System	10 Mar 2021 17:09:55
User entered 'No (N)'	System	10 Mar 2021 17:09:55

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-03-10T12:02:31', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '7b1c2ea9-8f49-454f-a898-2198cc2ec0c2' User entered '10 Mar 2021 12:02:31'	System	10 Mar 2021 17:09:55
	System	10 Mar 2021 17:09:55

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-03-17T10:44:37-04:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'e8df95be-0e14-43ea-bf61-7e36bd93f4da'	System	17 Mar 2021 14:45:10
User entered 'No (N)'	System	17 Mar 2021 14:45:10

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-03-17T10:44:41-04:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'e8df95be-0e14-43ea-bf61-7e36bd93f4da'	System	17 Mar 2021 14:45:10
User entered 'No (N)'	System	17 Mar 2021 14:45:10

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-03-17T10:45:06-04:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'e8df95be-0e14-43ea-bf61-7e36bd93f4da'	System	17 Mar 2021 14:45:10
User entered '17 Mar 2021 10:45:06'	System	17 Mar 2021 14:45:10

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-03-24T14:58:16-04:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '90af1c9f-2a2d-444b-90ea-5911755bf759'	System	24 Mar 2021 18:58:39
User entered 'No (N)'	System	24 Mar 2021 18:58:39

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-03-24T14:58:20-04:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '90af1c9f-2a2d-444b-90ea-5911755bf759'	System	24 Mar 2021 18:58:39
User entered 'No (N)'	System	24 Mar 2021 18:58:39

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-03-24T14:58:35-04:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '90af1c9f-2a2d-444b-90ea-5911755bf759'	System	24 Mar 2021 18:58:39
User entered '24 Mar 2021 14:58:35'	System	24 Mar 2021 18:58:39

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-03-31T00:43:39-04:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '94719b93-9ebc-450c-956d-e40cbc676742'	System	31 Mar 2021 04:44:07
User entered 'No (N)'	System	31 Mar 2021 04:44:07

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-03-31T00:43:44-04:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '94719b93-9ebc-450c-956d-e40cbc676742'	System	31 Mar 2021 04:44:07
User entered 'No (N)'	System	31 Mar 2021 04:44:07

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-03-31T00:44:03-04:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '94719b93-9ebc-450c-956d-e40cbc676742' User entered '31 Mar 2021 00:44:03'	System	31 Mar 2021 04:44:07
	System	31 Mar 2021 04:44:07

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-04-07T03:11:55-04:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '5e89b059-cd5a-4d58-843b-3d540c896b0c' User entered 'No (N)'	System	07 Apr 2021 07:12:13
	System	07 Apr 2021 07:12:13

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-04-07T03:11:59-04:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '5e89b059-cd5a-4d58-843b-3d540c896b0c' User entered 'No (N)'	System	07 Apr 2021 07:12:13

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-04-07T03:12:11-04:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '5e89b059-cd5a-4d58-843b-3d540c896b0c' User entered '07 Apr 2021 03:12:11'	System	07 Apr 2021 07:12:13
	System	07 Apr 2021 07:12:13

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-04-14T01:09:14-04:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '3d41191e-d375-4ffd-9e0d-63d3aa17cdef'	System	14 Apr 2021 05:09:54
User entered 'No (N)'	System	14 Apr 2021 05:09:54

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-04-14T01:09:28-04:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '3d41191e-d375-4ffd-9e0d-63d3aa17cdef'	System	14 Apr 2021 05:09:54
User entered 'No (N)'	System	14 Apr 2021 05:09:54

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-04-14T01:09:49-04:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '3d41191e-d375-4ffd-9e0d-63d3aa17cdef'	System	14 Apr 2021 05:09:54
User entered '14 Apr 2021 01:09:49'	System	14 Apr 2021 05:09:54

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-04-21T17:49:30-04:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '4277f67e-984c-4b5c-a583-26eca9ad8119'	System	21 Apr 2021 21:49:53
User entered 'No (N)'	System	21 Apr 2021 21:49:53

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-04-21T17:49:34-04:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '4277f67e-984c-4b5c-a583-26eca9ad8119' User entered 'No (N)'	System	21 Apr 2021 21:49:53

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-04-21T17:49:48-04:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: '4277f67e-984c-4b5c-a583-26eca9ad8119'	System	21 Apr 2021 21:49:53
User entered '21 Apr 2021 17:49:48'	System	21 Apr 2021 21:49:53

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-04-28T15:46:38-04:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'adf0ac50-2cf5-4ced-9414-efbc0b1fec55'	System	28 Apr 2021 22:17:12
User entered 'No (N)'	System	28 Apr 2021 22:17:12

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

Have you been exposed to someone with 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 (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-04-28T15:46:44-04:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'adf0ac50-2cf5-4ced-9414-efbc0b1fec55'	System	28 Apr 2021 22:17:12
User entered 'No (N)'	System	28 Apr 2021 22:17:12

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-04-28T15:46:56-04:00', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'adf0ac50-2cf5-4ced-9414-efbc0b1fec55'	System	28 Apr 2021 22:17:12
User entered '28 Apr 2021 15:46:56'	System	28 Apr 2021 22:17:12

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 08:55:23

US3482064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:55:23
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 08:55:23

US3482064

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:49:45

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)	24 Apr 2021 12:59:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-02-28T11:46:01', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'dd10a854-18d5-4cf7-b623-a26f5b60bd84'	System	28 Feb 2021 16:46:18
User entered 'No (N)'	System	28 Feb 2021 16:46:18

US3482064

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:49:45

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:59:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C21A41C-76F2-4C78-BA0A-563FA6497147)', Time: '2021-02-28T11:46:15', User OID: 'PatientReportedOutcome (US3482064)', ODM File OID: 'dd10a854-18d5-4cf7-b623-a26f5b60bd84' User entered '28 Feb 2021 11:46:15'	System	28 Feb 2021 16:46:18
	System	28 Feb 2021 16:46:18

US3482064

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:00:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:52:39

US3482064

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:00:06
User entered '9 Nov 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:52:39

US3482064

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:00:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:52:39

US3482064

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:00:06
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:52:39

US3482064

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:52:54

US3482064

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:55:42
User entered 'I'	System	12 Nov 2020 15:52:54

US3482064

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 19:29:04

US3482064

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 19:29:04

US3482064

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 19:29:04

US3482064

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 19:29:04

US3482064

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 19:29:10

US3482064

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User entered 'I'	System	14 Dec 2020 19:29:10

US3482064

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 14:56:17

US3482064

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 14:56:17

US3482064

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 14:56:17

US3482064

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 14:56:17

US3482064

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 14:56:23

US3482064

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User entered 'I'	System	12 Jan 2021 14:56:23

US3482064

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:29:35

US3482064

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:29:35

US3482064

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:29:35

US3482064

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:29:35

US3482064

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:29:41

US3482064

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User entered 'I'	System	12 Feb 2021 14:29:41

US3482064

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:00:06
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 17:49:37

US3482064

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:00:06
	(b) (4)	
User entered '12 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 17:49:37

US3482064

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

[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 10:22:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:00:06
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Mar 2021 17:49:37

US3482064

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:52
User entered 'VISIT4'	System	12 Mar 2021 17:49:37

US3482064

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:00:06
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 17:49:44

US3482064

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:00:06
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 17:49:44

US3482064

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:00:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 17:50:01

US3482064

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:00:06
	(b) (4)	
User entered '12 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 17:50:01

US3482064

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:00:06
	(b) (4)	
User entered '10:27'	(b) (4), (b) (6)	12 Mar 2021 17:50:01

US3482064

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:52
User entered '12 Mar 2021 10:27'	System	12 Mar 2021 17:50:01

US3482064

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:00:06
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 17:50:07

US3482064

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:22:52
User entered 'I'	System	12 Mar 2021 17:50:07

US3482064

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:10:33

US3482064

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:47
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:10:33

US3482064

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:10:33

US3482064

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:10:33

US3482064

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:18:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:10:40

US3482064

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 16:10:40

US3482064

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

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 17:20:28

US3482064

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

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 17:20:28

US3482064

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

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

[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 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 17:20:28

US3482064

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

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User entered 'UNBLND_DECIDE'	System	09 Jan 2021 17:20:28

US3482064

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

Form: Unblinding

Generated On: 11 Aug 2021 22:49:45

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 17:22:07

US3482064

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

Form: Unblinding

Generated On: 11 Aug 2021 22:49:45

[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 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:10:14
User entered '0'	(b) (4) Mari Hart (b) (4)	09 Apr 2021 14:53:06
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 12:51:05

US3482064

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

Form: Unblinding

Generated On: 11 Aug 2021 22:49:45

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	(b) (4)	
	System	11 Jan 2021 19:52:41
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered by data change (Site from System).	System	11 Jan 2021 19:52:41
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	09 Jan 2021 17:22:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Jan 2021 17:22:07

US3482064

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

Form: Unblinding

Generated On: 11 Aug 2021 22:49:45

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:10:14
User closed query ' 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 09:57:19
Query ' 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 14:53:13
User entered 'Amendment 6 or later (Amendment 6 or later)'	Mari Hart (b) (4) (b) (4)	09 Apr 2021 14:53:06
User opened query ' 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 14:08:55
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:51:05

US3482064

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

Form: Unblinding

Generated On: 11 Aug 2021 22:49:45

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 17:22:07

US3482064

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

Form: Unblinding

Generated On: 11 Aug 2021 22:49:45

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 17:22:07

US3482064

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

Form: Unblinding

Generated On: 11 Aug 2021 22:49:45

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 07:29:35
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	09 Jan 2021 17:22:07

US3482064

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

Form: Unblinding

Generated On: 11 Aug 2021 22:49:45

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Not Administered (NA)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:39:37
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 07:29:35
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:52:41
User entered empty.	(b) (4), (b) (6)	09 Jan 2021 17:22:07

US3482064

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

Form: Unblinding

Generated On: 11 Aug 2021 22:49:45

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 17:22:07

US3482064

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

Form: Unblinding

Generated On: 11 Aug 2021 22:49:45

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User entered empty.	System	09 Jan 2021 17:22:07

US3482064

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

Form: Unblinding

Generated On: 11 Aug 2021 22:49:45

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User entered 'I'	System	11 Jan 2021 19:52:41
User entered empty.	System	09 Jan 2021 17:22:07

US3482064

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:45

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User entered empty.	System	11 Jan 2021 19:55:03
DataPoint set to visible.	System	11 Jan 2021 19:52:41

US3482064

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:45

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User entered empty.	System	11 Jan 2021 19:55:03
DataPoint set to visible.	System	11 Jan 2021 19:52:41

US3482064

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '08 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '13:56'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User entered '08 Jan 2021 13:56'	System	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '70'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User entered 'bpm'	System	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '14'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User entered 'breaths/min'	System	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '109'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User entered 'mmHg'	System	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '76'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User entered 'mmHg'	System	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:45

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User entered empty.	System	11 Jan 2021 19:55:03
DataPoint set to visible.	System	11 Jan 2021 19:52:41

US3482064

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '08 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '15:58'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User entered '08 Jan 2021 15:58'	System	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '68'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User entered 'bpm'	System	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '16'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User entered 'breaths/min'	System	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '108'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User entered 'mmHg'	System	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '78'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:03

US3482064

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User entered 'mmHg'	System	11 Jan 2021 19:55:03

US3482064

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:14

US3482064

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '08 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:14

US3482064

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

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:41

US3482064

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

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:41

US3482064

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

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:41

US3482064

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

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User entered 'mRNA-1273'	System	11 Jan 2021 19:55:41
DataPoint set to visible.	System	11 Jan 2021 19:52:41

US3482064

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

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '08 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:41

US3482064

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

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '15:28'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:41

US3482064

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

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User entered '08 Jan 2021 15:28'	System	11 Jan 2021 19:55:41

US3482064

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

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:41

US3482064

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

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User entered 'ONCE'	System	11 Jan 2021 19:55:41

US3482064

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

Form: Exposure

Generated On: 11 Aug 2021 22:49:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User entered 'INTRAMUSCULAR'	System	11 Jan 2021 19:55:41

US3482064

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 17:24:43

US3482064

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 17:24:43

US3482064

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '13:49'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 17:24:43

US3482064

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User entered '8 Jan 2021 13:49'	System	09 Jan 2021 17:24:43

US3482064

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:49:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 17:24:58

US3482064

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:49:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 17:24:58

US3482064

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:49:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '13:53'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 17:24:58

US3482064

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:49:45

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User entered '8 Jan 2021 13:53'	System	09 Jan 2021 17:24:58

US3482064

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

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:55:54

US3482064

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

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:53
User entered 'I'	System	11 Jan 2021 19:55:54

US3482064

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:00:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:54:03

US3482064

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:00:06
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:54:03

US3482064

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:00:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:54:03

US3482064

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:00:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:54:03

US3482064

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:00:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:54:07

US3482064

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User entered 'I'	System	20 Jan 2021 19:54:07

US3482064

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:45

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User entered 'I'	System	20 Jan 2021 19:54:07
DataPoint set to visible.	System	20 Jan 2021 19:54:07

US3482064

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:09:22

US3482064

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:09:22

US3482064

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

[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 19:35:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:09:22

US3482064

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User entered 'OLD29'	System	04 Feb 2021 19:09:22

US3482064

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:09:36

US3482064

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:09:36

US3482064

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:09:36

US3482064

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User entered empty.	System	04 Feb 2021 19:09:36

US3482064

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:09:36

US3482064

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:09:36

US3482064

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:09:36

US3482064

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:09:36

US3482064

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User entered empty.	System	04 Feb 2021 19:09:36

US3482064

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:09:36

US3482064

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User entered empty.	System	04 Feb 2021 19:09:36

US3482064

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:09:36

US3482064

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User entered empty.	System	04 Feb 2021 19:09:36

US3482064

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:09:36

US3482064

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User entered empty.	System	04 Feb 2021 19:09:36

US3482064

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40

US3482064

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40

US3482064

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:09:43

US3482064

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:09:43

US3482064

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:10:04

US3482064

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:10:04

US3482064

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '13:50'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:10:04

US3482064

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:40
User entered '4 Feb 2021 13:50'	System	04 Feb 2021 19:10:04

US3482064

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:49:45

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:36
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:29:43

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User closed query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Right deltoid, etc), Type (e.g., Macular, Papular, etc) of ERYTHEMA and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:25:03
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash macular, LLT: Erythromacular rash - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:51:03
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:51:03
Data point term sent to Coder	System	24 Nov 2020 19:17:52
Query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Right deltoid, etc), Type (e.g., Macular, Papular, etc) of ERYTHEMA and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	Michele McCullough (b) (4)	24 Nov 2020 19:17:25
Coding entries removed.	Michele McCullough (b) (4)	24 Nov 2020 19:17:17
User entered 'non-urticarial macular rash with blanching erythema on left deltoid' reason for change: Per Query Resolution	Michele McCullough (b) (4)	24 Nov 2020 19:17:17
User opened query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Right deltoid, etc), Type (e.g., Macular, Papular, etc) of ERYTHEMA and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 02:32:08

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site erythema, LLT: Injection site erythema - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 06:15:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 06:15:50
Data point term sent to Coder	System	31 Aug 2020 21:36:24
User entered 'Grade 3 erythema at injection site'	(b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User closed query 'Per DM CLR: RQ: Response noted on query for start date. However, Was this a Solicited Adverse Reaction? = YES, however, the corresponding eDiary data for this symptom on this date is noted as NONE. Note that any SAR that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 09:52:27
Query 'Per DM CLR: RQ: Response noted on query for start date. However, Was this a Solicited Adverse Reaction? = YES, however, the corresponding eDiary data for this symptom on this date is noted as NONE. Note that any SAR that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 15:57:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 15:57:36
User opened query 'Per DM CLR: RQ: Response noted on query for start date. However, Was this a Solicited Adverse Reaction? = YES, however, the corresponding eDiary data for this symptom on this date is noted as NONE. Note that any SAR that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 02:15:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 21:36:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom Redness at injection Site on 17 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 09:50:55
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom Redness at injection Site on 17 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates.'	(b) (4), (b) (6)	15 Oct 2020 18:39:08
answered with 'There was zero erythema reported after 18-Aug-2020, the solicited event of redness was resolved during the reactogenicity period. She later developed redness on day 8, when there had previously been none' (Site from DM).		
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom Redness at injection Site on 17 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 02:46:36
User entered '25 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4) System	31 Aug 2020 21:36:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 21:36:52
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	31 Aug 2020 21:36:09
User entered '00:00'	(b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 21:36:52
User entered '25 Aug 2020 00:00'	System	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:43:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 21:36:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
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) System	25 Sep 2020 15:30:05
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	25 Sep 2020 15:30:05
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	08 Sep 2020 18:43:03
User entered '04 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 18:43:03
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:36:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User closed query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:24:43
Query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' answered with 'treatment discontinuation updated' (Site from DM).	Michele McCullough (b) (4)	24 Nov 2020 17:32:15
User opened query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 02:46:45
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

None

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	25 Sep 2020 15:35:08
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 15:35:08
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	08 Sep 2020 18:43:03
User entered '1'	(b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered '1' reason for change: New Information	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:43:03
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:30:05
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:13:08
User entered '71 yo female who received investigational product in left deltoid on 8/17/20. She had no symptoms for 7 days but on day 8 noted an area of erythema on left upper arm approx 3 cm in size. This progressively enlarged and became indurated and warm without pain or pruritis. On evaluation day 15 there was a 12 x5 cm well circumscribed rash over the left anterior upper arm, sparsely erythematous superiorly with blanching erythema and slight induration. No axillary adenopathy. Given location of the rash it is probably related to the study drug and could represent a delayed hypersensitivity reaction.'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	31 Aug 2020 21:36:09

US3482064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Aug 2020 21:36:09

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:49:45

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:40:34

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
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)	27 Aug 2020 19:46:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:46:02
Data point term sent to Coder	System	27 Aug 2020 18:05:03
Coding entries removed.	(b) (4), (b) (6)	27 Aug 2020 18:04:52
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.	Coder Import (b) (4)	18 Aug 2020 00:52:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 00:52:18
Data point term sent to Coder	System	17 Aug 2020 17:46:43
User entered 'levothyroxine'	(b) (4), (b) (6)	17 Aug 2020 17:46:02

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:46:02

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
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)	17 Nov 2020 09:25:56
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 'updated medical history' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 18:34:30
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)	04 Oct 2020 13:46:41
User entered 'HYPOTHYROIDISM' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 18:04:52
User entered 'hypothyroidsism'	(b) (4), (b) (6)	17 Aug 2020 17:46:02

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '88'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:46:02

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User closed query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as 'MCG'. Please confirm if any other suitable predefined option is available under the data field 'Frequency' for this medication and update as required. Otherwise please provide explanation.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:45:13
Query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as 'MCG'. Please confirm if any other suitable predefined option is available under the data field 'Frequency' for this medication and update as required. Otherwise please provide explanation.' answered with 'updated to ug since ug=mcg' (Site from DM).	Amy Anderson (b) (4) (b) (4)	25 Sep 2020 16:51:07
User entered 'ug (ug)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	25 Sep 2020 16:48:50
User opened query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as 'MCG'. Please confirm if any other suitable predefined option is available under the data field 'Frequency' for this medication and update as required. Otherwise please provide explanation.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 17:49:39
User entered 'Other (OTHER)'	(b) (4), (b) (6)	17 Aug 2020 17:46:02

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Amy Anderson (b) (4)	25 Sep 2020 16:48:50
	(b) (4)	
User entered 'mcg'	(b) (4), (b) (6)	17 Aug 2020 17:46:02

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:46:02

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:46:02

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:46:02

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:46:02

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:56:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 17:46:02
User entered 'un Dec 1968'	(b) (4), (b) (6)	17 Aug 2020 17:46:02

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:46:02

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:46:02

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:46:02

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 18:04:52
User entered 'No (N)' reason for change: Data Entry Error	System	27 Aug 2020 18:04:52
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	27 Aug 2020 18:04:52
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:46:02
		17 Aug 2020 17:46:02

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 17:46:02

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 17:46:02

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 17:46:02

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
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.	(b) (4) Coder Import (b) (4)	17 Aug 2020 17:48:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 17:48:20
Data point term sent to Coder	System	17 Aug 2020 17:47:48
User entered 'multivitamin'	(b) (4), (b) (6)	17 Aug 2020 17:47:13

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:47:13

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'prophylaxis'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:47:13

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '1'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:47:13

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:47:13

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:47:13

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:47:13

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:47:13

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:47:13

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:47:13

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:56:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 17:47:13
User entered 'un UNK 2010'	(b) (4), (b) (6)	17 Aug 2020 17:47:13

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:47:13

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:47:13

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:47:13

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:47:13

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 17:47:13

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 17:47:13

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 17:47:13

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM;VITAMIN D NOS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Aug 2020 10:15:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 10:15:36
Data point term sent to Coder	System	17 Aug 2020 17:49:56
User entered 'calcium/vitamin D'	(b) (4), (b) (6)	17 Aug 2020 17:49:10

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:45
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'updated per query resolution' (Site from DM).	Amy Anderson (b) (4) (b) (4)	05 Oct 2020 15:32:37
User entered 'No (N)' reason for change: Per Query Resolution	Amy Anderson (b) (4) (b) (4)	05 Oct 2020 15:32:23
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 13:47:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 17:49:10

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'osteopenia'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:49:10

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose/unit field. Please update the dose/unit to include both components as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 03:17:44
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose/unit field. Please update the dose/unit to include both components as applicable.' answered with 'updated' (Site from DM).	Michele McCullough (b) (4)	24 Nov 2020 17:44:29
User entered '600/800' reason for change: Per Query Resolution	Michele McCullough (b) (4)	24 Nov 2020 17:44:22
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose/unit field. Please update the dose/unit to include both components as applicable.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 08:33:37
User entered '600'	(b) (4), (b) (6)	17 Aug 2020 17:49:10

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
	(b) (4)	
User entered 'Other (OTHER)' reason for change: Per Query Resolution	Michele McCullough (b) (4)	24 Nov 2020 17:44:22
User entered 'mg (mg)'	(b) (4), (b) (6)	17 Aug 2020 17:49:10

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
	(b) (4)	
User entered 'mg/IU' reason for change: Data Entry Error	Michele McCullough (b) (4)	24 Nov 2020 17:44:22
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:49:10

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:49:10

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:49:10

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 17:49:19
User entered 'Oral (ORAL)' reason for change: Data Entry Error	System	17 Aug 2020 17:49:19
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 17:49:19
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 17:49:10

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:49:10

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:56:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 17:49:10
User entered 'un UNK 2018'	(b) (4), (b) (6)	17 Aug 2020 17:49:10

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:49:10

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:49:10

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:49:10

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:49:10

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 17:49:10

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 17:49:10

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 17:49:10

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Aug 2020 13:03:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 13:03:47
Data point term sent to Coder	System	27 Aug 2020 19:10:20
Coding entries removed.	(b) (4), (b) (6)	27 Aug 2020 19:10:17
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:28:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:28:15
Data point term sent to Coder	System	17 Aug 2020 22:26:42
User entered 'vitamin B-12'	(b) (4), (b) (6)	17 Aug 2020 22:25:56

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:25:56

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'prophylaxis' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 19:10:17
User entered 'supplement'	(b) (4), (b) (6)	17 Aug 2020 22:25:56

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '1'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:25:56

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:25:56

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:25:56

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:25:56

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:25:56

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:25:56

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:25:56

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 04:56:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 22:25:56
User entered 'un UNK 2019'	(b) (4), (b) (6)	17 Aug 2020 22:25:56

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:25:56

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:25:56

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:25:56

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 22:25:56

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 22:25:56

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 22:25:56

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 22:25:56

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	11 Dec 2020 04:00:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 04:00:48
Data point term sent to Coder	System	10 Dec 2020 23:29:34
Data point term sent to Coder	System	10 Dec 2020 19:44:08
Coding entries removed.	(b) (4), (b) (6)	10 Dec 2020 19:43:44
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:30:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:30:21
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: ACRIVASTINE, PRODUCTSYNONYM: BENADRYL [ACRIVASTINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 00:00:25

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:45

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	09 Sep 2020 00:00:25
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	08 Sep 2020 18:45:31
User entered 'benadryl'	(b) (4), (b) (6)	08 Sep 2020 18:45:09

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:45:09

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'INJECTION SITE REDNESS ON LEFT ARM AT VACCINE SITE (NON-URTICARIAL MACULAR RASH WITH BLANCHING ERYTHEMA ON LEFT DELTOID)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	10 Dec 2020 23:29:33
User entered 'injection site redness ON LEFT ARM AT VACCINE SITE' reason for change: Per Query Resolution	(b) (4), (b) (6)	10 Dec 2020 19:43:44
User entered 'rash on left arm at vaccine site'	(b) (4), (b) (6)	08 Sep 2020 18:45:09

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '25'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:45:09

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:45:09

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:45:09

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:45:09

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:45:09

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:45:09

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:45:09

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:45:09

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:45:09

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
Un-reviewed for Data Management.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 10:52:59
Reviewed for Data Management.	(b) (4), (b) (6)	01 Feb 2021 10:52:56
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 18:45:09

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:45:09

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 10:38:40
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' answered with 'Injection site redness at L deltoid, as recorded in eDiary, was reason for taking the medication. Indication clarified.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 19:44:46
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 06:41:21
User closed query 'Per DM CLR: Note, there is no any corresponding data on Diary or AE that matches this Con Med indication during indicated timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 03:16:51
Query 'Per DM CLR: Note, there is no any corresponding data on Diary or AE that matches this Con Med indication during indicated timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF.' answered with 'AE#1 resolved on 04Sep after subject took this medication for it on 03Sep, same timeframe' (Site from DM).	Michele McCullough (b) (4)	24 Nov 2020 17:49:09
User opened query 'Per DM CLR: Note, there is no any corresponding data on Diary or AE that matches this Con Med indication during indicated timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 20:49:42

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:45:09

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:43:46
User entered empty.	System	08 Sep 2020 18:45:09

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:43:46
User entered empty.	System	08 Sep 2020 18:45:09

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:43:46
User entered empty.	System	08 Sep 2020 18:45:09

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:47:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
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.	(b) (4)	
	Coder Import (b) (4)	25 Jan 2021 21:01:54
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 21:01:54
	(b) (4)	
Data point term sent to Coder	System	25 Jan 2021 21:00:35
User entered 'Seasonal Influenza Vaccine'	(b) (4), (b) (6)	25 Jan 2021 21:00:32

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:47:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:00:32

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:47:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Seasonal flu prevention'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:00:32

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:47:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '0.5'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:00:32

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:47:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:00:32

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:47:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:00:32

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:47:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:00:32

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:47:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:00:32

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:47:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:00:32

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:47:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:00:32

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:47:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '09 Nov 2020'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:00:32

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:47:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:00:32

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:47:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:00:32

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:47:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '09 Nov 2020'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:00:32

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:47:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:00:32

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:47:42
User entered empty.	System	25 Jan 2021 21:00:32

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:47:42
User entered empty.	System	25 Jan 2021 21:00:32

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:47:42
User entered empty.	System	25 Jan 2021 21:00:32

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:35:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: HYOSCINE, PRODUCTSYNONYM: SCOPOLAMINE [HYOSCINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coders Import (b) (4) (b) (4)	27 Jan 2021 00:17:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	27 Jan 2021 00:17:00
Data point term sent to Coders	System	26 Jan 2021 14:35:08
User entered 'Scopolamine'	(b) (4), (b) (6)	26 Jan 2021 14:34:34

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:35:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:34:34

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:35:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 12:05:33
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'MEDICATION IS RELATED TO ELECTIVE SURGERY IN CON PROCEDURES' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 21:17:14
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 01:47:13
User entered 'anti-nausea'	(b) (4), (b) (6)	26 Jan 2021 14:34:34

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:35:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '1.5'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:34:34

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:35:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:34:34

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:35:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:34:34

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:35:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:34:34

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:35:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:34:34

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:35:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Transdermal (TRANSDERMAL)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:34:34

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:35:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:34:34

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:35:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:34:34

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:35:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:34:34

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:35:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:34:34

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:35:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:34:34

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:35:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:34:34

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:35:42
User entered empty.	System	26 Jan 2021 14:34:34

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:35:42
User entered empty.	System	26 Jan 2021 14:34:34

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:35:42
User entered empty.	System	26 Jan 2021 14:34:34

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Jan 2021 00:19:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 00:19:55
Data point term sent to Coder	System	26 Jan 2021 14:36:08
User entered 'Propafol'	(b) (4), (b) (6)	26 Jan 2021 14:35:36

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:35:36

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 12:05:42
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'MEDICATION IS RELATED TO ELECTIVE SURGERY IN CON PROCEDURES' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 21:17:50
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 01:44:41
User entered 'anesthetic'	(b) (4), (b) (6)	26 Jan 2021 14:35:36

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '200'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:35:36

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:35:36

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:35:36

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:35:36

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:35:36

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:35:36

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:35:36

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:35:36

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:35:36

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:35:36

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:35:36

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:35:36

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:49
User entered empty.	System	26 Jan 2021 14:35:36

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:49
User entered empty.	System	26 Jan 2021 14:35:36

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:49
User entered empty.	System	26 Jan 2021 14:35:36

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:32:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Jan 2021 17:28:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 17:28:20
Data point term sent to Coder	System	26 Jan 2021 14:37:09
User entered 'Fentanyl'	(b) (4), (b) (6)	26 Jan 2021 14:36:15

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:32:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:36:15

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:32:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'anesthetic'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:36:15

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:32:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '100'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:36:15

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:32:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:36:15

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:32:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:36:15

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:32:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:36:15

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:32:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:36:15

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:32:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:36:15

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:32:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:36:15

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:32:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:36:15

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:32:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:36:15

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:32:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:36:15

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:32:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:36:15

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:32:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:36:15

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:32:21
User entered empty.	System	26 Jan 2021 14:36:15

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:32:21
User entered empty.	System	26 Jan 2021 14:36:15

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:32:21
User entered empty.	System	26 Jan 2021 14:36:15

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:51:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: HALOGENATED HYDROCARBONS, PRODUCT: SEVOFLURANE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Jan 2021 13:03:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 13:03:09
Data point term sent to Coder	System	26 Jan 2021 14:38:10
User entered 'Serofluane'	(b) (4), (b) (6)	26 Jan 2021 14:37:27

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:51:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:37:27

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:51:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 12:05:51
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'MEDICATION IS RELATED TO ELECTIVE SURGERY IN CON PROCEDURES' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 21:18:34
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 01:44:56
User entered 'anesthetic'	(b) (4), (b) (6)	26 Jan 2021 14:37:27

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:51:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:37:27

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:51:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'puff (PUFF)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:37:27

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:51:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:37:27

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:51:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:37:27

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:51:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:37:27

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:51:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:37:27

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:51:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:37:27

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:51:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:37:27

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:51:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:37:27

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:51:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:37:27

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:51:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:37:27

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:51:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:37:27

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:51:29
User entered empty.	System	26 Jan 2021 14:37:27

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:51:29
User entered empty.	System	26 Jan 2021 14:37:27

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:51:29
User entered empty.	System	26 Jan 2021 14:37:27

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Jan 2021 13:06:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 13:06:01
Data point term sent to Coder	System	26 Jan 2021 14:38:10
User entered 'Lidocaine'	(b) (4), (b) (6)	26 Jan 2021 14:38:01

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:01

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'anesthetic'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:01

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '60'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:01

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:01

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:01

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:01

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:01

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:01

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:01

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:01

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:01

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:01

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:01

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:01

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:10
User entered empty.	System	26 Jan 2021 14:38:01

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:10
User entered empty.	System	26 Jan 2021 14:38:01

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:06:10
User entered empty.	System	26 Jan 2021 14:38:01

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:21:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Jan 2021 00:23:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 00:23:59
Data point term sent to Coder	System	26 Jan 2021 14:39:11
User entered 'Ondansetron'	(b) (4), (b) (6)	26 Jan 2021 14:38:47

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:21:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:47

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:21:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 12:07:17
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'MEDICATION IS RELATED TO ELECTIVE SURGERY IN CON PROCEDURES' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 21:19:01
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 01:47:21
User entered 'anti-nausea'	(b) (4), (b) (6)	26 Jan 2021 14:38:47

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:21:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '4'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:47

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:21:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:47

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:21:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:47

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:21:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:47

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:21:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:47

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:21:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:47

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:21:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:47

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:21:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:47

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:21:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:47

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:21:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:47

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:21:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '24 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:47

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:21:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:38:47

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:21:51
User entered empty.	System	26 Jan 2021 14:38:47

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:21:51
User entered empty.	System	26 Jan 2021 14:38:47

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:21:51
User entered empty.	System	26 Jan 2021 14:38:47

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: OXYCODONE AND ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Jan 2021 00:22:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 00:22:59
Data point term sent to Coder	System	26 Jan 2021 14:40:12
User entered 'Oxycodone/Acetaminophen'	(b) (4), (b) (6)	26 Jan 2021 14:39:37

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:39:37

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 12:07:12
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'MEDICATION IS RELATED TO ELECTIVE SURGERY IN CON PROCEDURES' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 21:19:12
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 01:42:48
User entered 'pain management'	(b) (4), (b) (6)	26 Jan 2021 14:39:37

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '5-325'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:39:37

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:39:37

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:39:37

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:39:37

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:39:37

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:39:37

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:39:37

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:39:37

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:39:37

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:39:37

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:39:37

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:39:37

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:42
User entered empty.	System	26 Jan 2021 14:39:37

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:42
User entered empty.	System	26 Jan 2021 14:39:37

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:42
User entered empty.	System	26 Jan 2021 14:39:37

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL EXTRA STRENGTH - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Jan 2021 00:59:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 00:59:09
Data point term sent to Coder	System	26 Jan 2021 14:41:15
User entered 'Extra Strength Tylenol'	(b) (4), (b) (6)	26 Jan 2021 14:40:25

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:40:25

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 12:07:06
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'MEDICATION IS RELATED TO ELECTIVE SURGERY IN CON PROCEDURES' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 21:19:27
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 01:42:39
User entered 'pain management'	(b) (4), (b) (6)	26 Jan 2021 14:40:25

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '500'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:40:25

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:40:25

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:40:25

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:40:25

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:40:25

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:40:25

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:40:25

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:40:25

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:40:25

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:40:25

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:40:25

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:40:25

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 14:40:25

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 14:40:25

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 14:40:25

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:49:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:27:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Jan 2021 14:42:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 14:42:12
Data point term sent to Coder	System	26 Jan 2021 14:41:15
User entered 'Methocarbamol'	(b) (4), (b) (6)	26 Jan 2021 14:41:12

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:49:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:27:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:41:12

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:49:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:27:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 12:06:59
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'MEDICATION IS RELATED TO ELECTIVE SURGERY IN CON PROCEDURES' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 21:19:40
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 01:40:18
User entered 'muscle relaxer'	(b) (4), (b) (6)	26 Jan 2021 14:41:12

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:49:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:27:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '375'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:41:12

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:49:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:27:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:41:12

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:49:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:27:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:41:12

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:49:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:27:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:41:12

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:49:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:27:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:41:12

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:49:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:27:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:41:12

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:49:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:27:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:41:12

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:49:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:27:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:41:12

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:49:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:27:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:41:12

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:49:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:27:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:41:12

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:49:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:27:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '24 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:41:12

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:49:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:27:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:41:12

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:49:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:27:00
User entered empty.	System	26 Jan 2021 14:41:12

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:27:00
User entered empty.	System	26 Jan 2021 14:41:12

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:27:00
User entered empty.	System	26 Jan 2021 14:41:12

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:49:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:17:22
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFADROXIL, PRODUCTSYNONYM: DURICEF - version WHODrug-Global-B3\\202003.	(b) (4) Coders Import (b) (4) (b) (4)	28 Jan 2021 14:06:18
User coded data point as Term Coded data point by User: Coders System - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	28 Jan 2021 14:06:18
Data point term sent to Coders	System	28 Jan 2021 14:05:10
User entered 'Duricef'	(b) (4), (b) (6)	28 Jan 2021 14:04:52

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:49:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:17:22
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:20:09
User entered 'No (N)'	(b) (4), (b) (6)	28 Jan 2021 14:04:52

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:49:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:17:22
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 12:06:48
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'MEDICATION IS RELATED TO ELECTIVE SURGERY IN CON PROCEDURES' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 21:19:51
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 01:39:44
User entered 'antibiotic'	(b) (4), (b) (6)	28 Jan 2021 14:04:52

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:49:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:17:22
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '500'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:04:52

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:49:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:17:22
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jan 2021 14:05:02
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Jan 2021 14:05:02
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 14:04:52
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 14:04:52

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:49:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:17:22
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:04:52

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:49:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:17:22
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:04:52

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:49:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:17:22
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:04:52

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:49:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:17:22
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:04:52

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:49:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:17:22
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:04:52

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:49:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:17:22
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:04:52

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:49:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:17:22
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:04:52

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:49:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:17:22
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:04:52

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:49:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:17:22
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:04:52

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:49:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:17:22
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:04:52

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:49:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:17:22
User entered '2'	System	28 Jan 2021 14:04:52

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:17:22
User entered '1'	System	28 Jan 2021 14:04:52

US3482064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:49:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:17:22
User entered '804 (804)'	System	28 Jan 2021 14:04:52

US3482064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:49:45

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:54:17

US3482064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:49:45

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:02:19

US3482064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:49:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Bilateral explant surgery'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:02:19

US3482064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:49:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:02:19

US3482064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:49:45

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:21:33
User entered 'elective surgery'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:02:19

US3482064

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:49:45

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:14:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:59:11

US3482064

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:49:45

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:14:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:59:11

US3482064

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:49:45

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:14:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:59:55
User closed query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:24:03
Query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' answered with 'updated' (Site from DM).	Michele McCullough (b) (4)	24 Nov 2020 17:31:14
User entered 'AE#1' reason for change: Per Query Resolution	Michele McCullough (b) (4)	24 Nov 2020 17:31:08
User opened query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:10:47
User entered 'Physician Decision'	(b) (4), (b) (6)	21 Oct 2020 15:59:11