

US3482023 (Prod: Hope Clinic of The Emory Vaccine Center)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:45:43

All time stamps listed in this document are displayed in GMT

US3482023

Form: Participant Creation

Data signed: (b) (4) 01 Apr 2021 22:28:55

Generated On: 09 Jun 2021 17:45:43

[Participant ID](#)

US3482023

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

US3482023

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:06:23

Generated On: 09 Jun 2021 17:45:43

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

Visit date (dd MMM yyyy)	12 AUG 2020
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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	SCRN
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US3482023

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 15:06:23

Generated On: 09 Jun 2021 17:45:43

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	70
Age Units	YEARS
Age (Derived)	70
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	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 15:06:23

Generated On: 09 Jun 2021 17:45:43

Date of Informed Consent (<i>dd MMM yyyy</i>)	12 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

US3482023

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 15:06:23

Generated On: 09 Jun 2021 17:45:43

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 15:06:23

Generated On: 09 Jun 2021 17:45:43

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

Condition	LATERAL ILIOTIBIAL BAND SYNDROME
Start date (dd MMM yyyy)	UN JAN 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)	

US3482023

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN JAN 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3482023

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

Condition	R AND L CATARACT SURGERY
Start date (dd MMM yyyy)	UN JUL 2020
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 JUL 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUL 2020
Stop Year (derived)	2020

US3482023

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	JAN 1994
Stop Year (derived)	1994

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

Condition	ENDOMETRIOSIS
Start date (dd MMM yyyy)	UN UNK 1970
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 1994
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	JAN 1994
Stop Year (derived)	1994

US3482023

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

Condition	BOTOX FOR COSMETIC REASONS
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

US3482023

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 15:06:23

Generated On: 09 Jun 2021 17:45:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:06 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 09:06
Height (<i>xxx.x</i>)	61.5 in
Weight (<i>xxx.x</i>)	155 lb
BMI (<i>xxx.x</i>)	28.87296 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	79 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	65 mmHg
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 15:06:23

Generated On: 09 Jun 2021 17:45:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 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 15:06:23

Generated On: 09 Jun 2021 17:45:43

Date of assessment (dd MMM yyyy) 12 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) UN UNK 1994

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 15:06:23

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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 15:06:23

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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 15:06:23

Generated On: 09 Jun 2021 17:45:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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 15:06:23

Generated On: 09 Jun 2021 17:45:43

What was the date of randomization? (dd MMM yyyy) 24 AUG 2020

What was the participant's randomization number? 187455

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 15:06:23

Generated On: 09 Jun 2021 17:45:43

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 15:06:23

Generated On: 09 Jun 2021 17:45:43

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)	24 AUG 2020
Time of assessment (00:00-23:59)	08:45 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 08:45
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 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 15:06:23

Generated On: 09 Jun 2021 17:45:43

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)	24 AUG 2020
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 10:30
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)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 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 15:06:23

Generated On: 09 Jun 2021 17:45:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

US3482023

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 15:06:23

Generated On: 09 Jun 2021 17:45:43

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) 24 AUG 2020

What was the treatment time? (00:00-23:59) 09:54 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 09:54

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 15:06:23

Generated On: 09 Jun 2021 17:45:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 AUG 2020
Collection time (00:00-23:59)	08:55 (24 HR)
Collection date and time (derived)	24 AUG 2020 08:55

US3482023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 15:06:23

Generated On: 09 Jun 2021 17:45:43

Collection date (dd MMM yyyy)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:00	24 AUG 2020 09:00
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:06:23

Generated On: 09 Jun 2021 17:45:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 10:27

PC Open Date & Time

24 AUG 2020 10:14

PC Close Date & Time

24 AUG 2020 12:44

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

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 98.4 °F

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

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

PC Time Stamp	24 AUG 2020 17:12
PC Open Date & Time	24 AUG 2020 13:39
PC Close Date & Time	25 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:45:43

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

98.6 °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

25 AUG 2020 18:23

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 23:59

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

27 AUG 2020 22:54

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:45:43

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 17:07

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 16:52

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 17:45

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

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

24 AUG 2020 10:28

PC Open Date & Time

24 AUG 2020 10:14

PC Close Date & Time

24 AUG 2020 12:44

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 17:14

PC Open Date & Time

24 AUG 2020 13:39

PC Close Date & Time

25 AUG 2020 11:59

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 18:24

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 00:00

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:45:43

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

27 AUG 2020 22:54

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:45:43

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

28 AUG 2020 17:07

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:45:43

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

29 AUG 2020 16:52

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:45:43

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

30 AUG 2020 17:45

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 10:28
PC Open Date & Time	24 AUG 2020 10:14
PC Close Date & Time	24 AUG 2020 12:44

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 17:12
PC Open Date & Time	24 AUG 2020 13:39
PC Close Date & Time	25 AUG 2020 11:59

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

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 ☒

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 18:24
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

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 ☒

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 00:00
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2079

EAB) (1725)

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 22:55
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

54 of 2079

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 17:07
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

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 ☒

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 16:52
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

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

58 of 2079

EAB) (1725)

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 17:45
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3482023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:06:23

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:06:23

Generated On: 09 Jun 2021 17:45:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:06:23

Generated On: 09 Jun 2021 17:45:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482023

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:06:23

Generated On: 09 Jun 2021 17:45:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:06:23

Generated On: 09 Jun 2021 17:45:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482023

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:06:23

Generated On: 09 Jun 2021 17:45:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:07:44

Generated On: 09 Jun 2021 17:45:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 15:07:44

Generated On: 09 Jun 2021 17:45:43

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)	24 SEP 2020
Time of assessment (00:00-23:59)	08:20 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 08:20
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 15:07:44

Generated On: 09 Jun 2021 17:45:43

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)	24 SEP 2020
Time of assessment (00:00-23:59)	09:40 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 09:40
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3482023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:07:44

Generated On: 09 Jun 2021 17:45:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3482023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 15:07:44

Generated On: 09 Jun 2021 17:45:43

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) 24 SEP 2020

What was the treatment time? (00:00-23:59) 09:06 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 09:06

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

US3482023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:07:44

Generated On: 09 Jun 2021 17:45:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 SEP 2020

Collection time (00:00-23:59)

08:40 (24 HR)

Collection date and time (derived)

24 SEP 2020 08:40

US3482023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 15:06:23

Generated On: 09 Jun 2021 17:45:43

Collection date (dd MMM yyyy)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:42	24 SEP 2020 09:42
Nasopharyngeal Swab 2	No		

US3482023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:07:44

Generated On: 09 Jun 2021 17:45:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 09:37

PC Open Date & Time

24 SEP 2020 09:26

PC Close Date & Time

24 SEP 2020 11:56

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

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 98.3 °F

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

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

PC Time Stamp	25 SEP 2020 11:01
PC Open Date & Time	24 SEP 2020 12:51
PC Close Date & Time	25 SEP 2020 11:59

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:45:43

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

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

Yes ☐

No ☐

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 14:24

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 20:10

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:45:43

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 20:04

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 07:09

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 12:00

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

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

24 SEP 2020 09:52

PC Open Date & Time

24 SEP 2020 09:26

PC Close Date & Time

24 SEP 2020 11:56

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 11:00

PC Open Date & Time

24 SEP 2020 12:51

PC Close Date & Time

25 SEP 2020 11:59

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:45:43

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)**

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)**

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

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

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)**

2

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

26 SEP 2020 14:25

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

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.**

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

27 SEP 2020 20:11

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:45:43

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

28 SEP 2020 20:05

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:45:43

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

30 SEP 2020 07:09

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:45:43

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

30 SEP 2020 12:00

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 09:52
PC Open Date & Time	24 SEP 2020 09:26
PC Close Date & Time	24 SEP 2020 11:56

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 11:01
PC Open Date & Time	24 SEP 2020 12:51
PC Close Date & Time	25 SEP 2020 11:59

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

Yes ☐

PC Time stamp

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

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 ☒

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 14:24
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

98 of 2079

EAB) (1725)

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 20:10
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

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

100 of 2079

EAB) (1725)

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 20:04
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

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 ☒

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 07:09
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

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

104 of 2079

EAB) (1725)

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 12:39
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3482023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:06:23

Generated On: 09 Jun 2021 17:45:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482023

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:06:23

Generated On: 09 Jun 2021 17:45:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:06:23

Generated On: 09 Jun 2021 17:45:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482023

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:06:23

Generated On: 09 Jun 2021 17:45:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:06:23

Generated On: 09 Jun 2021 17:45:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482023

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:06:23

Generated On: 09 Jun 2021 17:45:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:07:44

Generated On: 09 Jun 2021 17:45:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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

US3482023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 15:07:44

Generated On: 09 Jun 2021 17:45:43

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) _____

US3482023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:07:44

Generated On: 09 Jun 2021 17:45:43

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.

US3482023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:07:44

Generated On: 09 Jun 2021 17:45:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 OCT 2020
Collection time (00:00-23:59)	08:20 (24 HR)
Collection date and time (derived)	21 OCT 2020 08:20

US3482023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:07:44

Generated On: 09 Jun 2021 17:45:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

27 OCT 2020 10:22:44

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

31 OCT 2020 00:01:42

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 NOV 2020 13:03:09

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 NOV 2020 00:01:30
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

03 DEC 2020 23:20:26

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 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"/>

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

18 DEC 2020 17:59:47

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 13:08:11

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

[Patient Cloud Open Date & Time](#)

30 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 JAN 2021 12:47:36
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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	13 JAN 2021 02:02:51
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

20 JAN 2021 20:28:42

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 JAN 2021 09:21:03
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 22:09:59

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 <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	10 FEB 2021 22:59:23
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 18:07:20

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 05:01:31
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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	03 MAR 2021 00:02:42
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 14:03:02

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

18 MAR 2021 12:22:44

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

24 MAR 2021 18:41:28

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

02 APR 2021 12:15:12

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

09 APR 2021 14:02:38

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 APR 2021 20:18:19
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 243

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

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

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

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

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

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

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

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

28 APR 2021 08:20:11

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 306

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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"/>

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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"/>

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

Patient Cloud Open Date & Time	20 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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
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Patient Cloud Close Date & Time	31 OCT 2021 23:59
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US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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="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"/>

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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°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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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°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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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°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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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"/>

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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°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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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°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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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°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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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"/>

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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"/>

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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"/>

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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="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"/>

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

[Patient Cloud Open Date & Time](#)

26 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3482023

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:45:43

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
Yes	No	03 MAR 2021 00:03:18

US3482023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 22:28:55

Generated On: 09 Jun 2021 17:45:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482023

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 22:28:55

Generated On: 09 Jun 2021 17:45:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 22:28:55

Generated On: 09 Jun 2021 17:45:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3482023

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 22:28:55

Generated On: 09 Jun 2021 17:45:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 22:28:55

Generated On: 09 Jun 2021 17:45:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3482023

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 22:28:55

Generated On: 09 Jun 2021 17:45:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 22:28:55

Generated On: 09 Jun 2021 17:45:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3482023

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 22:28:55

Generated On: 09 Jun 2021 17:45:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 22:28:55

Generated On: 09 Jun 2021 17:45:43

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

Visit date (dd MMM yyyy)	23 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
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US3482023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 22:28:55

Generated On: 09 Jun 2021 17:45:43

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) _____

US3482023

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 22:28:55

Generated On: 09 Jun 2021 17:45:43

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.

US3482023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 22:28:55

Generated On: 09 Jun 2021 17:45:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 MAR 2021
Collection time (00:00-23:59)	08:43 (24 HR)
Collection date and time (derived)	23 MAR 2021 08:43

US3482023

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 22:28:55

Generated On: 09 Jun 2021 17:45:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3482023

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482023

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3482023

Folder: Covid-19 Assessment 28 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 01 Apr 2021 22:28:55

Generated On: 09 Jun 2021 17:45:43

Date of Contact	28 JAN 2021
Time of Contact	09:46
Date and Time of Contact (derived)	28 JAN 2021 09:46
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input checked="" type="checkbox"/></div>

US3482023

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

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 22:28:55

Generated On: 09 Jun 2021 17:45:43

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

Visit date (dd MMM yyyy)	23 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	UNBLND_DECIDE
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US3482023

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

Form: Unblinding

Data signed: (b) (4) 17 Apr 2021 03:07:55

Generated On: 09 Jun 2021 17:45:43

Date of updated informed consent (<i>dd MMM yyyy</i>)	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	True
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 checked="" type="radio"/> Amendment 6 or later <input type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	28 DEC 2020
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 checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	

US3482023

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 22:28:55

Generated On: 09 Jun 2021 17:45:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 MAR 2021

Collection time (00:00-23:59)

08:43 (24 HR)

Collection date and time (derived)

23 MAR 2021 08:43

US3482023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 01 Apr 2021 22:28:55

Generated On: 09 Jun 2021 17:45:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 MAR 2021
Collection time (00:00 - 23:59)	08:38
Collection Date and Time (derived)	23 MAR 2021 08:38

US3482023

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 03:10:32

Generated On: 09 Jun 2021 17:45:43

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 03:10:32

Generated On: 09 Jun 2021 17:45:43

AEID	USA-US106-2020-MRNA-1273-P30 1000003
Adverse event	EPIGASTRIC PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	4 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	5 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	4 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	5 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 03:10:32

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 03:10:32

Generated On: 09 Jun 2021 17:45:43

70 YEAR OLD ADMITTED ON
11/04/20 AND DISCHARGED
11/5/20 WITH EPIGASTRIC PAIN
LIKELY DUE TO GALL STONES.
PAIN MEDICATION PROVIDED
ALONG WITH PROTON PUMP
INHIBITOR WITH EDG
PLANNED AS OUTPATIENT.
SAE NOT RELATED TO STUDY
PROTOCOL.

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

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Mar 2021 22:18:18

Generated On: 09 Jun 2021 17:45:43

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

Yes ☒

No ☐

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

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

Name of Medication LOSARTAN

Prophylaxis Yes ☒
No ☐

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

Name of Medication CYMBALTA

Prophylaxis Yes ☒
No ☐

Indication LATERAL ILIOTIBIAL BAND
SYNDROME

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

Name of Medication VIT D

Prophylaxis Yes ☐

No ☒

Indication SUPPLEMENT

Dose per administration 2500

Dose unit mg ☐

ug ☐

mL ☐

g ☐

IU ☒

tablet ☐

capsule ☐

puff ☐

Other ☐

If dose unit is Other, specify

Frequency once daily ☐

twice daily ☒

three times daily ☐

four times daily ☐

every other day ☐

every week ☐

every month ☐

as needed ☐

once ☐

unknown ☐

other ☐

If frequency is Other, specify

Route of administration Oral ☒

Topical ☐

Subcutaneous ☐

Transdermal ☐

Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

	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 JAN 2009	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

Name of Medication ZINC

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

Name of Medication TURMERIC CURCUMIN

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

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 (5)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 03:22:18

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Name of Medication ADIPEX-P

Prophylaxis Yes ☐
No ☒

Indication WEIGHT CONTROL

Dose per administration 37.5

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 (6)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

	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 JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	06 JUL 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 03:22:18

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Name of Medication BIO COMPLEX 3 PROBIOTIC

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

	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 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

Name of Medication BESIVANCE OPHTHALMIC

Prophylaxis Yes ☐
No ☒

Indication CATARACT SURGERY

Dose per administration 1

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

If dose unit is Other, specify DROP

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) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

	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)	06 JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

Name of Medication PROLENSA

Prophylaxis Yes ☐
No ☒

Indication CATARACT SURGERY

Dose per administration 1

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

If dose unit is Other, specify DROP

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) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

	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)	16 JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 03:22:18

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Name of Medication LOTEMAX

Prophylaxis Yes ☒
No ☐

Indication POST CATARACT SURGERY

Dose per administration 1

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

If dose unit is Other, specify DROP

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) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

	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)	30 JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 03:22:18

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Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		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 (12)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

Name of Medication COLOLITE

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 03:22:18

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

Name of Medication FLU SHOT

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		11 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 03:22:18

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Name of Medication DILAUDID

Prophylaxis Yes ☐
No ☒

Indication EPIGASTRIC PAIN
MANAGEMENT

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY FOUR HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

	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 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)		4 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)		5 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 (15)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

Name of Medication PROTONIX(PANTOPRAZOLE)

Prophylaxis Yes ☐
No ☒

Indication EPIGASTRIC PAIN
MANAGEMENT

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

Name of Medication ENOXAPARIN

Prophylaxis Yes ☒
No ☐

Indication DVT PROPHYLAXIS

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

	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)		4 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)		5 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

Name of Medication ESTRADIOL

Prophylaxis Yes ☐
No ☒

Indication HORMONE REPLACEMENT

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 ☐
Intraocular ☐

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EAB) (1725)

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 03:22:18

Generated On: 09 Jun 2021 17:45:43

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

US3482023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Mar 2021 22:18:18

Generated On: 09 Jun 2021 17:45:43

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3482023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Mar 2021 22:18:18

Generated On: 09 Jun 2021 17:45:43

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
09 FEB 2021	GALLBLADDER REMOVAL	Adverse Event	

US3482023

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:45:43

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3482023

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:45:43

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 ☐

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 26 Mar 2021 22:18:18

Generated On: 09 Jun 2021 17:45:43

SAEID	USA-US106-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Mar 2021 22:18:18

Generated On: 09 Jun 2021 17:45:43

SAEID	USA-US106-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	16/NOV/2020 22:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Mar 2021 22:18:18

Generated On: 09 Jun 2021 17:45:43

SAEID	USA-US106-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	25/NOV/2020 12:14
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Mar 2021 22:18:18

Generated On: 09 Jun 2021 17:45:43

SAEID	USA-US106-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/FEB/2021 10:06
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Mar 2021 22:18:18

Generated On: 09 Jun 2021 17:45:43

SAEID	USA-US106-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/FEB/2021 10:52
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3482023 (Prod: Hope Clinic of The Emory Vaccine Center)

US3482023

Form: Participant Creation

Generated On: 09 Jun 2021 17:45:43

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'US3482023'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 12:34:34

US3482023

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:15:05

US3482023

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '12 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 12:34:35

US3482023

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

[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 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:15:05

US3482023

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered 'SCRN'	System	14 Aug 2020 14:15:05

US3482023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:45:43

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered (b) (6) 1950'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 12:34:35

US3482023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:45:43

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '70'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:15:57

US3482023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:45:43

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered 'YEARS'	System	14 Aug 2020 14:15:57

US3482023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:45:43

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered '70'	System	24 Aug 2020 14:02:04

US3482023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:45:43

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:15:57

US3482023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:45:43

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:15:57

US3482023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:45:43

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:15:57

US3482023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:45:43

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:15:57

US3482023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:45:43

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:15:57

US3482023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:45:43

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:15:57

US3482023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:45:43

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:15:57

US3482023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:45:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:15:57

US3482023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:45:43

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:15:57

US3482023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:45:43

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:15:57

US3482023

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:45:43

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:15:57

US3482023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:45:43

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:02:04

US3482023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered 'Aug 2020'	System	24 Aug 2020 14:02:04

US3482023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered '2020'	System	24 Aug 2020 14:02:04

US3482023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:45:43

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Amendment 1 (1)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:02:04

US3482023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:02:04

US3482023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:45:43

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:02:04

US3482023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:45:43

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:02:04

US3482023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:45:43

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:33:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 14:02:04

US3482023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:45:43

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User closed query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	(b) (4) System	10 Sep 2020 15:33:07
Comment added 'UD3482023'.	(b) (4), (b) (6)	24 Aug 2020 14:03:35
User opened query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	24 Aug 2020 14:02:04
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 12:34:35

US3482023

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:45:43

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered 'I'	System	24 Aug 2020 14:04:17

US3482023

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:04:17

US3482023

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:45:43

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:08:24

US3482023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:45:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User closed query 'Per DM CLR: Please specify the location of the LATERAL ILIOTIBIAL BAND SYNDROME (e.g. right, left side) . Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:00:45
Query 'Per DM CLR: Please specify the location of the LATERAL ILIOTIBIAL BAND SYNDROME (e.g. right, left side) . Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated with correct info' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 18:28:18
User opened query 'Per DM CLR: Please specify the location of the LATERAL ILIOTIBIAL BAND SYNDROME (e.g. right, left side) . Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 21:04:32
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Iliotibial band syndrome, LLT: Iliotibial band syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 10:34:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 10:34:44
Data point term sent to Coder	System	24 Aug 2020 18:11:55
User entered 'Lateral iliotibial band syndrome'	(b) (4), (b) (6)	24 Aug 2020 18:11:32

US3482023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'UN Jan 2015' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	29 Sep 2020 18:28:01
User entered 'un Feb 2019'	(b) (4), (b) (6)	24 Aug 2020 18:11:32

US3482023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:45:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:11:32

US3482023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:45:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:11:32

US3482023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:11:32

US3482023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:45:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:11:32

US3482023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered 'Jan 2015'	System	29 Sep 2020 18:28:01
User entered 'Feb 2019'	System	24 Aug 2020 18:11:32

US3482023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered '2015'	System	29 Sep 2020 18:28:01
User entered '2019'	System	24 Aug 2020 18:11:32

US3482023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered empty.	System	24 Aug 2020 18:11:32

US3482023

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered empty.	System	24 Aug 2020 18:11:32

US3482023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:45:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Aug 2020 18:14:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 18:14:35
Data point term sent to Coder	System	24 Aug 2020 18:13:59
User entered 'Hypertension'	(b) (4), (b) (6)	24 Aug 2020 18:13:00

US3482023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'un Jan 2008'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:13:00

US3482023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:45:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:13:00

US3482023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:45:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:13:00

US3482023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:13:00

US3482023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:45:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:13:00

US3482023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered 'Jan 2008'	System	24 Aug 2020 18:13:00

US3482023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered '2008'	System	24 Aug 2020 18:13:00

US3482023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered empty.	System	24 Aug 2020 18:13:00

US3482023

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered empty.	System	24 Aug 2020 18:13:00

US3482023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:45:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	25 Aug 2020 09:48:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 09:48:42
Data point term sent to Coder	System	24 Aug 2020 18:15:05
User entered 'R and L Cataract surgery'	(b) (4), (b) (6)	24 Aug 2020 18:14:02

US3482023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'un Jul 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:14:02

US3482023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:45:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:14:02

US3482023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:45:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
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	24 Aug 2020 18:14:12
User entered 'No (N)' reason for change: Data Entry Error	System	24 Aug 2020 18:14:12
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	24 Aug 2020 18:14:02
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 18:14:02

US3482023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'un Jul 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:14:02

US3482023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:45:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:14:02

US3482023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered 'Jul 2020'	System	24 Aug 2020 18:14:02

US3482023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:45:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered '2020'	System	24 Aug 2020 18:14:02

US3482023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered 'Jul 2020'	System	24 Aug 2020 18:14:02

US3482023

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered '2020'	System	24 Aug 2020 18:14:02

US3482023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:45:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:48:11
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:45:53
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 21:04:46
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 18:22:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 18:22:40
Data point term sent to Coder	System	24 Aug 2020 18:21:35
User entered 'Hysterectomy'	(b) (4), (b) (6)	24 Aug 2020 18:21:10

US3482023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'un UNK 1994'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:21:10

US3482023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:45:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:21:10

US3482023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:45:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:21:10

US3482023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'un UNK 1994'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:21:10

US3482023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:45:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:21:10

US3482023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:45:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered 'Jan 1994'	System	24 Aug 2020 18:21:10

US3482023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:45:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered '1994'	System	24 Aug 2020 18:21:10

US3482023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered 'Jan 1994'	System	24 Aug 2020 18:21:10

US3482023

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered '1994'	System	24 Aug 2020 18:21:10

US3482023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:45:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User coded data point as SOC: Reproductive system and breast disorders, HLG: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 16:02:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 16:02:47
Data point term sent to Coder	System	08 Oct 2020 12:47:32
User entered 'Endometriosis'	(b) (4), (b) (6)	08 Oct 2020 12:46:35

US3482023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'un UNK 1970'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:46:35

US3482023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:45:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:46:35

US3482023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:45:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:46:35

US3482023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'un UNK 1994'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:46:35

US3482023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:45:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:46:35

US3482023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered 'Jan 1970'	System	08 Oct 2020 12:46:35

US3482023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered '1970'	System	08 Oct 2020 12:46:35

US3482023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered 'Jan 1994'	System	08 Oct 2020 12:46:35

US3482023

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered '1994'	System	08 Oct 2020 12:46:35

US3482023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:45:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:18
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Botulinum toxin injection, LLT: Botulinum toxin injection - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 14:56:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 14:56:59
Data point term sent to Coder	System	20 Apr 2021 14:55:32
Coding entries removed.	Amy Anderson (b) (4)	20 Apr 2021 14:55:09
Signature has been broken.	(b) (4)	
	Amy Anderson (b) (4)	20 Apr 2021 14:55:09
User entered 'Botox for cosmetic reasons' reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Cornification and dystrophic skin disorders, HLT: Skin dystrophies, PT: Skin wrinkling, LLT: Skin wrinkling - version MedDRA\\23.0.	Coder Import (b) (4)	01 Apr 2021 19:29:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Apr 2021 19:29:07
Data point term sent to Coder	System	01 Apr 2021 19:28:17
User entered 'facial wrinkles'	Mari Hart (b) (4)	01 Apr 2021 19:28:15
	(b) (4)	

US3482023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'un UNK 2000'	Mari Hart (b) (4)	01 Apr 2021 19:28:15

US3482023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:45:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered '0'	Mari Hart (b) (4)	01 Apr 2021 19:28:15

US3482023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:45:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'No (N)'	Mari Hart (b) (4)	01 Apr 2021 19:28:15

US3482023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'un UNK 2000'	(b) (4) Mari Hart (b) (4)	01 Apr 2021 19:28:15

US3482023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:45:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered '0'	Mari Hart (b) (4)	01 Apr 2021 19:28:15

US3482023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered 'Jan 2000'	System	01 Apr 2021 19:28:15

US3482023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered '2000'	System	01 Apr 2021 19:28:15

US3482023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered 'Jan 2000'	System	01 Apr 2021 19:28:15

US3482023

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered '2000'	System	01 Apr 2021 19:28:15

US3482023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:16:57

US3482023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:16:57

US3482023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '09:06'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:16:57

US3482023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered '12 Aug 2020 09:06'	System	24 Aug 2020 18:16:57

US3482023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '61.5' in	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:16:57
DataPoint set to visible.	System	24 Aug 2020 14:04:17

US3482023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '155' lb	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:16:57
DataPoint set to visible.	System	24 Aug 2020 14:04:17

US3482023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
Amendment Manager: User entered '28.87296'	System	16 Sep 2020 23:52:59
User entered '28.9'	System	24 Aug 2020 18:16:57
DataPoint set to visible.	System	24 Aug 2020 14:04:17

US3482023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered 'kg/m2'	System	24 Aug 2020 18:16:57
DataPoint set to visible.	System	24 Aug 2020 14:04:17

US3482023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:16:57

US3482023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:16:57

US3482023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:16:57

US3482023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '79'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:16:57

US3482023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered 'bpm'	System	24 Aug 2020 18:16:57

US3482023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '16'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:16:57

US3482023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered 'breaths/min'	System	24 Aug 2020 18:16:57

US3482023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '118'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:16:57

US3482023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered 'mmHg'	System	24 Aug 2020 18:16:57

US3482023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '65'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:16:57

US3482023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User entered 'mmHg'	System	24 Aug 2020 18:16:57

US3482023

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22

US3482023

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:45:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:17:11

US3482023

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:45:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
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)	27 Aug 2020 13:46:33
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	24 Aug 2020 18:28:57
User entered '12 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 18:18:15
User entered '24 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 18:17:11

US3482023

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:45:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:19:23

US3482023

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:19:23

US3482023

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:45:43

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:19:23

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:45:43

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:19:23

US3482023

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'un UNK 1994'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:19:23

US3482023

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:45:43

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:19:23

US3482023

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:19:23

US3482023

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:45:43

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:19:23

US3482023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:45:43

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 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:24:57

US3482023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:45:43

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 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:24:57

US3482023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:45:43

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 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:24:57

US3482023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:45:43

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 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:24:57

US3482023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:45:43

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 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:24:57

US3482023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:45:43

[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 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:24:57

US3482023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:45:43

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 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:24:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:45:43

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 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:24:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:45:43

[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 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:24:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:45:43

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 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:24:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:45:43

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 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:24:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:45:43

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:24:57

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:24:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:45:43

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:24:57

US3482023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:24:57

US3482023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:45:43

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 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:24:57

US3482023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:45:43

[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 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:24:57

US3482023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:45:43

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 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:24:57

US3482023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:24:57

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:24:57

US3482023

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:45:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Resident in a community with ongoing person to person transmission'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:24:57

US3482023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:28:57

US3482023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:28:57

US3482023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

[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 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:28:57

US3482023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User entered 'VISIT1'	System	24 Aug 2020 18:28:57

US3482023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 13:19:57

US3482023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '187455'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 13:19:57

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 13:19:57

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:45:43

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 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:00:00

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:45:43

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 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:00:00

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:00:00

US3482023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:45:43

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:00:00

US3482023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:45:43

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:00:00

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:45:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:45:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:45:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:45:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '08:45'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User entered '24 Aug 2020 08:45'	System	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '79'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User entered 'bpm'	System	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '20'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User entered 'breaths/min'	System	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '110'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User entered 'mmHg'	System	24 Aug 2020 18:41:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '70'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User entered 'mmHg'	System	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:45:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:45:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
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	24 Aug 2020 18:44:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 18:44:40
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 18:41:15
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 18:41:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '10:30'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User entered '24 Aug 2020 10:30'	System	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '71'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User entered 'bpm'	System	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '19'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User entered 'breaths/min'	System	24 Aug 2020 18:41:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '128'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:41:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User entered 'mmHg'	System	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '78' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Aug 2020 18:28:47
User entered '74'	(b) (4), (b) (6)	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User entered 'mmHg'	System	24 Aug 2020 18:41:15

US3482023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:45:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:44:50

US3482023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:45:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:44:50

US3482023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:45:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:10:45

US3482023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:45:43

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:10:45

US3482023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:45:43

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 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:10:45

US3482023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:45:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 14:10:45

US3482023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:45:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:10:45

US3482023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:45:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '09:54'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:10:45

US3482023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:45:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User entered '24 Aug 2020 09:54'	System	24 Aug 2020 14:10:45

US3482023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:45:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Aug 2020 18:27:56
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	24 Aug 2020 14:10:45

US3482023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:45:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User entered 'ONCE'	System	24 Aug 2020 14:10:45

US3482023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:45:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 14:10:45

US3482023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:45:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:45:28

US3482023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:45:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:45:28

US3482023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:45:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '08:55'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:45:28

US3482023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:45:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User entered '24 Aug 2020 08:55'	System	24 Aug 2020 18:45:28

US3482023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:45:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:46:11

US3482023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:45:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	24 Aug 2020 18:46:11

US3482023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:45:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:46:11

US3482023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:45:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '09:00'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:46:11

US3482023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:45:43

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User entered '24 Aug 2020 09:00'	System	24 Aug 2020 18:46:11

US3482023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:45:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	24 Aug 2020 18:46:11

US3482023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:45:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
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	24 Aug 2020 18:46:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 18:46:16
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 18:46:11
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 18:46:11

US3482023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:45:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:46:11

US3482023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:45:43

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User entered empty.	System	24 Aug 2020 18:46:11

US3482023

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:46:25

US3482023

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User entered 'I'	System	24 Aug 2020 18:46:25

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T10:27:10', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'c43951be-75fc-424b-845f-0b07d83c0ca9' User entered 'Yes (Y)'	System	24 Aug 2020 14:27:27
	System	24 Aug 2020 14:27:27

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T10:27:15', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'c43951be-75fc-424b-845f-0b07d83c0ca9' User entered '98.1'	System	24 Aug 2020 14:27:27
	System	24 Aug 2020 14:27:27

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T10:27:21', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'c43951be-75fc-424b-845f-0b07d83c0ca9'	System	24 Aug 2020 14:27:27
User entered 'No (N)'	System	24 Aug 2020 14:27:27

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T10:27:25', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'c43951be-75fc-424b-845f-0b07d83c0ca9' User entered '24 Aug 2020 10:27'	System	24 Aug 2020 14:27:27
	System	24 Aug 2020 14:27:27

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '24 Aug 2020 10:14'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '24 Aug 2020 12:44'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T17:11:47', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'bf024f7f-0d0f-4a45-ba24-b371c3326d04'	System	24 Aug 2020 21:12:06
User entered 'Yes (Y)'	System	24 Aug 2020 21:12:06

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T17:11:52', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'bf024f7f-0d0f-4a45-ba24-b371c3326d04'	System	24 Aug 2020 21:12:06
User entered '98.4'	System	24 Aug 2020 21:12:06

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T17:11:56', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'bf024f7f-0d0f-4a45-ba24-b371c3326d04'	System	24 Aug 2020 21:12:06
User entered 'No (N)'	System	24 Aug 2020 21:12:06

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T17:12:03', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'bf024f7f-0d0f-4a45-ba24-b371c3326d04'	System	24 Aug 2020 21:12:06
User entered '24 Aug 2020 17:12'	System	24 Aug 2020 21:12:06

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '24 Aug 2020 13:39'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 2'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:45:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-25T18:22:35', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '08ef836f-0c86-4547-bdaf-bdbda84a23bf' User entered 'Yes (Y)'	System	25 Aug 2020 22:23:53
	System	25 Aug 2020 22:23:53

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:45:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-25T18:23:41', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '08ef836f-0c86-4547-bdaf-bdbda84a23bf' User entered '98.6'	System	25 Aug 2020 22:23:53
	System	25 Aug 2020 22:23:53

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-25T18:23:44', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '08ef836f-0c86-4547-bdaf-bdbda84a23bf'	System	25 Aug 2020 22:23:53
User entered 'No (N)'	System	25 Aug 2020 22:23:53

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-25T18:23:51', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '08ef836f-0c86-4547-bdaf-bdbda84a23bf' User entered '25 Aug 2020 18:23'	System	25 Aug 2020 22:23:53
	System	25 Aug 2020 22:23:53

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 3'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:45:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-26T23:59:24', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '063da0f3-4658-4838-a03f-28ac9fbb0e78' User entered 'Yes (Y)'	System	27 Aug 2020 03:59:51
	System	27 Aug 2020 03:59:51

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:45:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-26T23:59:36', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '063da0f3-4658-4838-a03f-28ac9fbb0e78' User entered '98.2'	System	27 Aug 2020 03:59:51
	System	27 Aug 2020 03:59:51

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-26T23:59:39', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '063da0f3-4658-4838-a03f-28ac9fbb0e78' User entered 'No (N)'	System	27 Aug 2020 03:59:51
	System	27 Aug 2020 03:59:51

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-26T23:59:44', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '063da0f3-4658-4838-a03f-28ac9fbb0e78' User entered '26 Aug 2020 23:59'	System	27 Aug 2020 03:59:51
	System	27 Aug 2020 03:59:51

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 4'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:45:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T22:54:30', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '360fdeff-8fe3-40d0-96e9-07301180b837'	System	28 Aug 2020 02:54:49
User entered 'Yes (Y)'	System	28 Aug 2020 02:54:49

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:45:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T22:54:35', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '360fdeff-8fe3-40d0-96e9-07301180b837' User entered '98.1'	System	28 Aug 2020 02:54:49
	System	28 Aug 2020 02:54:49

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T22:54:38', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '360fdeff-8fe3-40d0-96e9-07301180b837'	System	28 Aug 2020 02:54:49
User entered 'No (N)'	System	28 Aug 2020 02:54:49

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T22:54:47', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '360fdeff-8fe3-40d0-96e9-07301180b837'	System	28 Aug 2020 02:54:49
User entered '27 Aug 2020 22:54'	System	28 Aug 2020 02:54:49

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 5'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:45:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-28T17:07:04', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '5c359737-9db5-4299-b42e-9ef1813acd8b' User entered 'Yes (Y)'	System	28 Aug 2020 21:07:19
	System	28 Aug 2020 21:07:19

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:45:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-28T17:07:09', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '5c359737-9db5-4299-b42e-9ef1813acd8b' User entered '98.4'	System	28 Aug 2020 21:07:19
	System	28 Aug 2020 21:07:19

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-28T17:07:14', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '5c359737-9db5-4299-b42e-9ef1813acd8b' User entered 'No (N)'	System	28 Aug 2020 21:07:19
	System	28 Aug 2020 21:07:19

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-28T17:07:16', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '5c359737-9db5-4299-b42e-9ef1813acd8b' User entered '28 Aug 2020 17:07'	System	28 Aug 2020 21:07:19
	System	28 Aug 2020 21:07:19

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 6'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:45:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-29T16:52:01', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'b8096190-7143-4512-86f0-cf9ebe06bcbe' User entered 'Yes (Y)'	System	29 Aug 2020 20:52:21
	System	29 Aug 2020 20:52:21

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:45:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-29T16:52:09', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'b8096190-7143-4512-86f0-cf9ebe06bcbe' User entered '98.2'	System	29 Aug 2020 20:52:21
	System	29 Aug 2020 20:52:21

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-29T16:52:14', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'b8096190-7143-4512-86f0-cf9ebe06bcbe' User entered 'No (N)'	System	29 Aug 2020 20:52:21
	System	29 Aug 2020 20:52:21

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-29T16:52:20', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'b8096190-7143-4512-86f0-cf9ebe06bcbe' User entered '29 Aug 2020 16:52'	System	29 Aug 2020 20:52:21
	System	29 Aug 2020 20:52:21

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 7'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:45:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-30T17:45:21', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '20d04d41-895e-4d1a-b2df-60a9549be90c'	System	30 Aug 2020 21:45:35
User entered 'Yes (Y)'	System	30 Aug 2020 21:45:35

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:45:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-30T17:45:27', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '20d04d41-895e-4d1a-b2df-60a9549be90c' User entered '98.2'	System	30 Aug 2020 21:45:35
	System	30 Aug 2020 21:45:35

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-30T17:45:29', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '20d04d41-895e-4d1a-b2df-60a9549be90c'	System	30 Aug 2020 21:45:35
User entered 'No (N)'	System	30 Aug 2020 21:45:35

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-30T17:45:32', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '20d04d41-895e-4d1a-b2df-60a9549be90c' User entered '30 Aug 2020 17:45'	System	30 Aug 2020 21:45:35
	System	30 Aug 2020 21:45:35

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T10:28:08', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1d4fade6-269c-496b-8300-785e144881f1' User entered 'None (1)'	System	24 Aug 2020 14:28:32
	System	24 Aug 2020 14:28:32

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T10:28:16', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1d4fade6-269c-496b-8300-785e144881f1' User entered 'No (N)'	System	24 Aug 2020 14:28:32
	System	24 Aug 2020 14:28:32

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T10:28:20', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1d4fade6-269c-496b-8300-785e144881f1' User entered 'No (N)'	System	24 Aug 2020 14:28:32
	System	24 Aug 2020 14:28:32

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T10:28:25', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1d4fade6-269c-496b-8300-785e144881f1' User entered 'None (1)'	System	24 Aug 2020 14:28:32
	System	24 Aug 2020 14:28:32

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T10:28:29', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1d4fade6-269c-496b-8300-785e144881f1' User entered '24 Aug 2020 10:28'	System	24 Aug 2020 14:28:32
	System	24 Aug 2020 14:28:32

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '24 Aug 2020 10:14'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '24 Aug 2020 12:44'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T17:10:53', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '5ebc0413-70fe-4de5-9dd2-a430dc0b31c5' User entered 'None (1)'	System	24 Aug 2020 21:14:15
	System	24 Aug 2020 21:14:15

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T17:14:03', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '5ebc0413-70fe-4de5-9dd2-a430dc0b31c5'	System	24 Aug 2020 21:14:15
User entered 'No (N)'	System	24 Aug 2020 21:14:15

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T17:14:06', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '5ebc0413-70fe-4de5-9dd2-a430dc0b31c5'	System	24 Aug 2020 21:14:15
User entered 'No (N)'	System	24 Aug 2020 21:14:15

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T17:14:08', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '5ebc0413-70fe-4de5-9dd2-a430dc0b31c5' User entered 'None (1)'	System	24 Aug 2020 21:14:15
	System	24 Aug 2020 21:14:15

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T17:14:12', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '5ebc0413-70fe-4de5-9dd2-a430dc0b31c5'	System	24 Aug 2020 21:14:15
User entered '24 Aug 2020 17:14'	System	24 Aug 2020 21:14:15

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '24 Aug 2020 13:39'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 2'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-25T18:24:16', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '3979954a-2757-4e44-b503-a847f27d3b77'	System	25 Aug 2020 22:24:31
User entered 'None (1)'	System	25 Aug 2020 22:24:31

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:45:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-25T18:24:20', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '3979954a-2757-4e44-b503-a847f27d3b77'	System	25 Aug 2020 22:24:31
User entered 'No (N)'	System	25 Aug 2020 22:24:31

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-25T18:24:22', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '3979954a-2757-4e44-b503-a847f27d3b77'	System	25 Aug 2020 22:24:31
User entered 'No (N)'	System	25 Aug 2020 22:24:31

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-25T18:24:24', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '3979954a-2757-4e44-b503-a847f27d3b77'	System	25 Aug 2020 22:24:31
User entered 'None (1)'	System	25 Aug 2020 22:24:31

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-25T18:24:28', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '3979954a-2757-4e44-b503-a847f27d3b77'	System	25 Aug 2020 22:24:31
User entered '25 Aug 2020 18:24'	System	25 Aug 2020 22:24:31

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 3'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-26T23:59:50', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'f1962831-acd4-45c8-a404-27c1ecef828a' User entered 'None (1)'	System	27 Aug 2020 04:00:07
	System	27 Aug 2020 04:00:07

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:45:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-26T23:59:52', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'f1962831-acd4-45c8-a404-27c1ecef828a' User entered 'No (N)'	System	27 Aug 2020 04:00:07
	System	27 Aug 2020 04:00:07

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-26T23:59:55', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'f1962831-acd4-45c8-a404-27c1ecef828a' User entered 'No (N)'	System	27 Aug 2020 04:00:07
	System	27 Aug 2020 04:00:07

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-26T23:59:58', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'f1962831-acd4-45c8-a404-27c1ecef828a' User entered 'None (1)'	System	27 Aug 2020 04:00:07
	System	27 Aug 2020 04:00:07

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T00:00:02', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'f1962831-acd4-45c8-a404-27c1ecef828a' User entered '27 Aug 2020 00:00'	System	27 Aug 2020 04:00:07
	System	27 Aug 2020 04:00:07

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 4'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T22:54:14', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '90b127a4-790f-4ecb-89e2-309c5b7acea7' User entered 'None (1)'	System	28 Aug 2020 02:54:30
	System	28 Aug 2020 02:54:30

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:45:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T22:54:17', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '90b127a4-790f-4ecb-89e2-309c5b7acea7' User entered 'No (N)'	System	28 Aug 2020 02:54:30
	System	28 Aug 2020 02:54:30

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T22:54:19', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '90b127a4-790f-4ecb-89e2-309c5b7acea7' User entered 'No (N)'	System	28 Aug 2020 02:54:30
	System	28 Aug 2020 02:54:30

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T22:54:21', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '90b127a4-790f-4ecb-89e2-309c5b7acea7' User entered 'None (1)'	System	28 Aug 2020 02:54:30
	System	28 Aug 2020 02:54:30

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T22:54:24', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '90b127a4-790f-4ecb-89e2-309c5b7acea7' User entered '27 Aug 2020 22:54'	System	28 Aug 2020 02:54:30
	System	28 Aug 2020 02:54:30

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 5'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-28T17:07:20', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'f584f6b4-76e4-4286-927c-ef2e670d44a0' User entered 'None (1)'	System	28 Aug 2020 21:07:33
	System	28 Aug 2020 21:07:33

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:45:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-28T17:07:22', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'f584f6b4-76e4-4286-927c-ef2e670d44a0'	System	28 Aug 2020 21:07:33
User entered 'No (N)'	System	28 Aug 2020 21:07:33

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-28T17:07:24', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'f584f6b4-76e4-4286-927c-ef2e670d44a0' User entered 'No (N)'	System	28 Aug 2020 21:07:33
	System	28 Aug 2020 21:07:33

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-28T17:07:27', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'f584f6b4-76e4-4286-927c-ef2e670d44a0' User entered 'None (1)'	System	28 Aug 2020 21:07:33
	System	28 Aug 2020 21:07:33

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-28T17:07:29', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'f584f6b4-76e4-4286-927c-ef2e670d44a0' User entered '28 Aug 2020 17:07'	System	28 Aug 2020 21:07:33
	System	28 Aug 2020 21:07:33

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 6'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-29T16:52:24', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'f70e8f1f-732c-4639-80eb-13beff532213' User entered 'None (1)'	System	29 Aug 2020 20:52:38
	System	29 Aug 2020 20:52:38

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:45:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-29T16:52:27', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'f70e8f1f-732c-4639-80eb-13beff532213' User entered 'No (N)'	System	29 Aug 2020 20:52:38
	System	29 Aug 2020 20:52:38

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-29T16:52:29', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'f70e8f1f-732c-4639-80eb-13beff532213' User entered 'No (N)'	System	29 Aug 2020 20:52:38
	System	29 Aug 2020 20:52:38

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-29T16:52:32', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'f70e8f1f-732c-4639-80eb-13beff532213' User entered 'None (1)'	System	29 Aug 2020 20:52:38
	System	29 Aug 2020 20:52:38

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-29T16:52:35', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'f70e8f1f-732c-4639-80eb-13beff532213' User entered '29 Aug 2020 16:52'	System	29 Aug 2020 20:52:38
	System	29 Aug 2020 20:52:38

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 7'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-30T17:45:35', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '3a946bad-4897-4608-9343-97a939329553'	System	30 Aug 2020 21:45:46
User entered 'None (1)'	System	30 Aug 2020 21:45:46

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:45:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-30T17:45:38', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '3a946bad-4897-4608-9343-97a939329553'	System	30 Aug 2020 21:45:46
User entered 'No (N)'	System	30 Aug 2020 21:45:46

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-30T17:45:40', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '3a946bad-4897-4608-9343-97a939329553'	System	30 Aug 2020 21:45:46
User entered 'No (N)'	System	30 Aug 2020 21:45:46

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-30T17:45:42', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '3a946bad-4897-4608-9343-97a939329553'	System	30 Aug 2020 21:45:46
User entered 'None (1)'	System	30 Aug 2020 21:45:46

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-30T17:45:45', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '3a946bad-4897-4608-9343-97a939329553'	System	30 Aug 2020 21:45:46
User entered '30 Aug 2020 17:45'	System	30 Aug 2020 21:45:46

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T10:27:36', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ca222d0f-c737-46a3-add7-3e5d6dfadd42' User entered 'None (0)'	System	24 Aug 2020 14:28:08
	System	24 Aug 2020 14:28:08

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T10:27:38', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ca222d0f-c737-46a3-add7-3e5d6dfadd42'	System	24 Aug 2020 14:28:08
User entered 'Some interference with activity (2)'	System	24 Aug 2020 14:28:08

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T10:27:44', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ca222d0f-c737-46a3-add7-3e5d6dfadd42' User entered 'None (0)'	System	24 Aug 2020 14:28:08
	System	24 Aug 2020 14:28:08

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T10:27:46', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ca222d0f-c737-46a3-add7-3e5d6dfadd42' User entered 'None (0)'	System	24 Aug 2020 14:28:08
	System	24 Aug 2020 14:28:08

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T10:27:48', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ca222d0f-c737-46a3-add7-3e5d6dfadd42' User entered 'None (0)'	System	24 Aug 2020 14:28:08
	System	24 Aug 2020 14:28:08

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T10:27:50', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ca222d0f-c737-46a3-add7-3e5d6dfadd42' User entered 'None (0)'	System	24 Aug 2020 14:28:08
	System	24 Aug 2020 14:28:08

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T10:27:52', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ca222d0f-c737-46a3-add7-3e5d6dfadd42'	System	24 Aug 2020 14:28:08
User entered 'No (N)'	System	24 Aug 2020 14:28:08

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T10:28:04', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ca222d0f-c737-46a3-add7-3e5d6dfadd42'	System	24 Aug 2020 14:28:08
User entered '24 Aug 2020 10:28'	System	24 Aug 2020 14:28:08

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '24 Aug 2020 10:14'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '24 Aug 2020 12:44'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T17:12:13', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1358def1-d915-4f9f-bd37-30754286a83e' User entered 'None (0)'	System	24 Aug 2020 21:12:30
	System	24 Aug 2020 21:12:30

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T17:12:14', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1358def1-d915-4f9f-bd37-30754286a83e' User entered 'None (0)'	System	24 Aug 2020 21:12:30
	System	24 Aug 2020 21:12:30

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T17:12:16', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1358def1-d915-4f9f-bd37-30754286a83e' User entered 'None (0)'	System	24 Aug 2020 21:12:30
	System	24 Aug 2020 21:12:30

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T17:12:17', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1358def1-d915-4f9f-bd37-30754286a83e' User entered 'None (0)'	System	24 Aug 2020 21:12:30
	System	24 Aug 2020 21:12:30

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T17:12:19', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1358def1-d915-4f9f-bd37-30754286a83e' User entered 'None (0)'	System	24 Aug 2020 21:12:30
	System	24 Aug 2020 21:12:30

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T17:12:20', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1358def1-d915-4f9f-bd37-30754286a83e' User entered 'None (0)'	System	24 Aug 2020 21:12:30
	System	24 Aug 2020 21:12:30

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T17:12:22', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1358def1-d915-4f9f-bd37-30754286a83e' User entered 'No (N)'	System	24 Aug 2020 21:12:30
	System	24 Aug 2020 21:12:30

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-24T17:12:28', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1358def1-d915-4f9f-bd37-30754286a83e' User entered '24 Aug 2020 17:12'	System	24 Aug 2020 21:12:30
	System	24 Aug 2020 21:12:30

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '24 Aug 2020 13:39'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 2'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-25T18:23:56', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '988a7760-2af2-49ef-85a1-e15fa2bd75fb' User entered 'None (0)'	System	25 Aug 2020 22:24:12
	System	25 Aug 2020 22:24:12

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-25T18:23:57', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '988a7760-2af2-49ef-85a1-e15fa2bd75fb' User entered 'None (0)'	System	25 Aug 2020 22:24:12
	System	25 Aug 2020 22:24:12

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-25T18:23:59', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '988a7760-2af2-49ef-85a1-e15fa2bd75fb' User entered 'None (0)'	System	25 Aug 2020 22:24:12
	System	25 Aug 2020 22:24:12

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-25T18:24:01', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '988a7760-2af2-49ef-85a1-e15fa2bd75fb' User entered 'None (0)'	System	25 Aug 2020 22:24:12
	System	25 Aug 2020 22:24:12

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-25T18:24:03', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '988a7760-2af2-49ef-85a1-e15fa2bd75fb' User entered 'None (0)'	System	25 Aug 2020 22:24:12
	System	25 Aug 2020 22:24:12

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-25T18:24:04', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '988a7760-2af2-49ef-85a1-e15fa2bd75fb' User entered 'None (0)'	System	25 Aug 2020 22:24:12
	System	25 Aug 2020 22:24:12

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-25T18:24:06', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '988a7760-2af2-49ef-85a1-e15fa2bd75fb' User entered 'No (N)'	System	25 Aug 2020 22:24:12
	System	25 Aug 2020 22:24:12

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-25T18:24:09', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '988a7760-2af2-49ef-85a1-e15fa2bd75fb' User entered '25 Aug 2020 18:24'	System	25 Aug 2020 22:24:12
	System	25 Aug 2020 22:24:12

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 3'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T00:00:06', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'dfa94c7a-ec1e-44a9-9071-f1ce788eb223' User entered 'None (0)'	System	27 Aug 2020 04:00:20
	System	27 Aug 2020 04:00:20

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T00:00:07', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'dfa94c7a-ec1e-44a9-9071-f1ce788eb223' User entered 'None (0)'	System	27 Aug 2020 04:00:20
	System	27 Aug 2020 04:00:20

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T00:00:09', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'dfa94c7a-ec1e-44a9-9071-f1ce788eb223' User entered 'None (0)'	System	27 Aug 2020 04:00:20
	System	27 Aug 2020 04:00:20

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T00:00:10', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'dfa94c7a-ec1e-44a9-9071-f1ce788eb223' User entered 'None (0)'	System	27 Aug 2020 04:00:20
	System	27 Aug 2020 04:00:20

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T00:00:12', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'dfa94c7a-ec1e-44a9-9071-f1ce788eb223' User entered 'None (0)'	System	27 Aug 2020 04:00:20
	System	27 Aug 2020 04:00:20

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T00:00:14', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'dfa94c7a-ec1e-44a9-9071-f1ce788eb223' User entered 'None (0)'	System	27 Aug 2020 04:00:20
	System	27 Aug 2020 04:00:20

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T00:00:15', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'dfa94c7a-ec1e-44a9-9071-f1ce788eb223'	System	27 Aug 2020 04:00:20
User entered 'No (N)'	System	27 Aug 2020 04:00:20

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T00:00:18', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'dfa94c7a-ec1e-44a9-9071-f1ce788eb223' User entered '27 Aug 2020 00:00'	System	27 Aug 2020 04:00:20
	System	27 Aug 2020 04:00:20

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 4'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T22:54:50', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '81215411-3b07-4978-9ef1-291699a840fc' User entered 'None (0)'	System	28 Aug 2020 02:55:06
	System	28 Aug 2020 02:55:06

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T22:54:52', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '81215411-3b07-4978-9ef1-291699a840fc' User entered 'None (0)'	System	28 Aug 2020 02:55:06
	System	28 Aug 2020 02:55:06

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T22:54:53', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '81215411-3b07-4978-9ef1-291699a840fc' User entered 'None (0)'	System	28 Aug 2020 02:55:06
	System	28 Aug 2020 02:55:06

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T22:54:54', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '81215411-3b07-4978-9ef1-291699a840fc' User entered 'None (0)'	System	28 Aug 2020 02:55:06
	System	28 Aug 2020 02:55:06

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T22:54:56', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '81215411-3b07-4978-9ef1-291699a840fc' User entered 'None (0)'	System	28 Aug 2020 02:55:06
	System	28 Aug 2020 02:55:06

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T22:54:57', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '81215411-3b07-4978-9ef1-291699a840fc' User entered 'None (0)'	System	28 Aug 2020 02:55:06
	System	28 Aug 2020 02:55:06

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T22:54:58', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '81215411-3b07-4978-9ef1-291699a840fc' User entered 'No (N)'	System	28 Aug 2020 02:55:06
	System	28 Aug 2020 02:55:06

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-27T22:55:01', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '81215411-3b07-4978-9ef1-291699a840fc' User entered '27 Aug 2020 22:55'	System	28 Aug 2020 02:55:06
	System	28 Aug 2020 02:55:06

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 5'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-28T17:07:33', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '7aff6296-bf16-4456-a0e6-b241259de96b' User entered 'None (0)'	System	28 Aug 2020 21:07:46
	System	28 Aug 2020 21:07:46

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-28T17:07:34', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '7aff6296-bf16-4456-a0e6-b241259de96b' User entered 'None (0)'	System	28 Aug 2020 21:07:46
	System	28 Aug 2020 21:07:46

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-28T17:07:35', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '7aff6296-bf16-4456-a0e6-b241259de96b' User entered 'None (0)'	System	28 Aug 2020 21:07:46
	System	28 Aug 2020 21:07:46

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-28T17:07:37', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '7aff6296-bf16-4456-a0e6-b241259de96b' User entered 'None (0)'	System	28 Aug 2020 21:07:46
	System	28 Aug 2020 21:07:46

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-28T17:07:38', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '7aff6296-bf16-4456-a0e6-b241259de96b' User entered 'None (0)'	System	28 Aug 2020 21:07:46
	System	28 Aug 2020 21:07:46

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-28T17:07:39', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '7aff6296-bf16-4456-a0e6-b241259de96b' User entered 'None (0)'	System	28 Aug 2020 21:07:46
	System	28 Aug 2020 21:07:46

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-28T17:07:41', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '7aff6296-bf16-4456-a0e6-b241259de96b' User entered 'No (N)'	System	28 Aug 2020 21:07:46
	System	28 Aug 2020 21:07:46

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-28T17:07:44', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '7aff6296-bf16-4456-a0e6-b241259de96b' User entered '28 Aug 2020 17:07'	System	28 Aug 2020 21:07:46
	System	28 Aug 2020 21:07:46

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 6'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-29T16:52:39', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1d8c2125-5157-41b8-a77d-43874ce4de9d' User entered 'None (0)'	System	29 Aug 2020 20:52:52
	System	29 Aug 2020 20:52:52

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-29T16:52:41', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1d8c2125-5157-41b8-a77d-43874ce4de9d' User entered 'None (0)'	System	29 Aug 2020 20:52:52
	System	29 Aug 2020 20:52:52

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-29T16:52:42', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1d8c2125-5157-41b8-a77d-43874ce4de9d' User entered 'None (0)'	System	29 Aug 2020 20:52:52
	System	29 Aug 2020 20:52:52

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-29T16:52:44', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1d8c2125-5157-41b8-a77d-43874ce4de9d' User entered 'None (0)'	System	29 Aug 2020 20:52:52
	System	29 Aug 2020 20:52:52

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-29T16:52:45', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1d8c2125-5157-41b8-a77d-43874ce4de9d' User entered 'None (0)'	System	29 Aug 2020 20:52:52
	System	29 Aug 2020 20:52:52

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-29T16:52:46', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1d8c2125-5157-41b8-a77d-43874ce4de9d' User entered 'None (0)'	System	29 Aug 2020 20:52:52
	System	29 Aug 2020 20:52:52

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-29T16:52:48', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1d8c2125-5157-41b8-a77d-43874ce4de9d'	System	29 Aug 2020 20:52:52
User entered 'No (N)'	System	29 Aug 2020 20:52:52

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-29T16:52:51', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1d8c2125-5157-41b8-a77d-43874ce4de9d' User entered '29 Aug 2020 16:52'	System	29 Aug 2020 20:52:52
	System	29 Aug 2020 20:52:52

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 7'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-30T17:45:48', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'bbc9a16a-5fbc-4802-b975-3ac5f37db194' User entered 'None (0)'	System	30 Aug 2020 21:46:01
	System	30 Aug 2020 21:46:01

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-30T17:45:50', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'bbc9a16a-5fbc-4802-b975-3ac5f37db194' User entered 'None (0)'	System	30 Aug 2020 21:46:01
	System	30 Aug 2020 21:46:01

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-30T17:45:51', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'bbc9a16a-5fbc-4802-b975-3ac5f37db194' User entered 'None (0)'	System	30 Aug 2020 21:46:01
	System	30 Aug 2020 21:46:01

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-30T17:45:53', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'bbc9a16a-5fbc-4802-b975-3ac5f37db194' User entered 'None (0)'	System	30 Aug 2020 21:46:01
	System	30 Aug 2020 21:46:01

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-30T17:45:54', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'bbc9a16a-5fbc-4802-b975-3ac5f37db194' User entered 'None (0)'	System	30 Aug 2020 21:46:01
	System	30 Aug 2020 21:46:01

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-30T17:45:55', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'bbc9a16a-5fbc-4802-b975-3ac5f37db194' User entered 'None (0)'	System	30 Aug 2020 21:46:01
	System	30 Aug 2020 21:46:01

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-30T17:45:57', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'bbc9a16a-5fbc-4802-b975-3ac5f37db194' User entered 'No (N)'	System	30 Aug 2020 21:46:01
	System	30 Aug 2020 21:46:01

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-08-30T17:45:59', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'bbc9a16a-5fbc-4802-b975-3ac5f37db194' User entered '30 Aug 2020 17:45'	System	30 Aug 2020 21:46:01
	System	30 Aug 2020 21:46:01

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 14:10:45

US3482023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 14:30:47

US3482023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 14:30:47

US3482023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 14:30:47

US3482023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 14:30:47

US3482023

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 14:30:58

US3482023

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User entered 'I'	System	09 Sep 2020 14:30:58

US3482023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 14:31:31

US3482023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '07 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:52:18
User entered '7 Sep 2020'	(b) (4), (b) (6)	09 Sep 2020 14:31:31

US3482023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 14:31:31

US3482023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 14:31:31

US3482023

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 14:31:38

US3482023

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:00:54
User entered 'I'	System	09 Sep 2020 14:31:38

US3482023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:20:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 15:05:24

US3482023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:20:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 15:05:24

US3482023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:20:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 15:05:24

US3482023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:20:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 15:05:24

US3482023

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:20:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 15:05:31

US3482023

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:20:04
User entered 'I'	System	14 Sep 2020 15:05:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:52:21

US3482023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:52:21

US3482023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

[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 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:52:21

US3482023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered 'VISIT2'	System	24 Sep 2020 14:52:21

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered '08:20'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered '24 Sep 2020 08:20'	System	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered '84'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered 'bpm'	System	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered '18'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered 'breaths/min'	System	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered '137'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered 'mmHg'	System	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered '77'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:45:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered 'mmHg'	System	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered '09:40'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered '24 Sep 2020 09:40'	System	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered '81'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered 'bpm'	System	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered '19'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered 'breaths/min'	System	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered '132'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered 'mmHg'	System	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered '75'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:45:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered 'mmHg'	System	24 Sep 2020 14:55:31

US3482023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:45:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:52:32

US3482023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:45:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:52:32

US3482023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:45:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 13:26:40

US3482023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:45:43

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 13:26:40

US3482023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:45:43

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 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 13:26:40

US3482023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:45:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 13:26:40

US3482023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:45:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 13:26:40

US3482023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:45:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered '09:06'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 13:26:40

US3482023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:45:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered '24 Sep 2020 09:06'	System	24 Sep 2020 13:26:40

US3482023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:45:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 13:26:40

US3482023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:45:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered 'ONCE'	System	24 Sep 2020 13:26:40

US3482023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:45:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 13:26:40

US3482023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:45:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:52:55

US3482023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:45:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:52:55

US3482023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:45:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered '08:40'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:52:55

US3482023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:45:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered '24 Sep 2020 08:40'	System	24 Sep 2020 14:52:55

US3482023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:45:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:53:15

US3482023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:45:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	24 Sep 2020 14:53:15

US3482023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:45:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:53:15

US3482023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:45:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '09:42'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:53:15

US3482023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:45:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered '24 Sep 2020 09:42'	System	24 Sep 2020 14:53:15

US3482023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:45:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	24 Sep 2020 14:53:15

US3482023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:45:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:53:15

US3482023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:45:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:53:15

US3482023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:45:43

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered empty.	System	24 Sep 2020 14:53:15

US3482023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:53:22

US3482023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered 'I'	System	24 Sep 2020 14:53:22

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-24T09:36:53', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ed3ff8c6-20b0-49b1-8263-f64703bff6ca' User entered 'Yes (Y)'	System	24 Sep 2020 13:37:37
	System	24 Sep 2020 13:37:37

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-24T09:37:23', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ed3ff8c6-20b0-49b1-8263-f64703bff6ca' User entered '98.3'	System	24 Sep 2020 13:37:37
	System	24 Sep 2020 13:37:37

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-24T09:37:26', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ed3ff8c6-20b0-49b1-8263-f64703bff6ca' User entered 'No (N)'	System	24 Sep 2020 13:37:37
	System	24 Sep 2020 13:37:37

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-24T09:37:31', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ed3ff8c6-20b0-49b1-8263-f64703bff6ca' User entered '24 Sep 2020 09:37'	System	24 Sep 2020 13:37:37
	System	24 Sep 2020 13:37:37

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '24 Sep 2020 09:26'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '24 Sep 2020 11:56'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-25T11:01:03', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'b04e650b-be46-41da-b2f7-461dfb3d86af' User entered 'Yes (Y)'	System	25 Sep 2020 15:01:16
	System	25 Sep 2020 15:01:16

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-25T11:01:08', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'b04e650b-be46-41da-b2f7-461dfb3d86af' User entered '98.3'	System	25 Sep 2020 15:01:16
	System	25 Sep 2020 15:01:16

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-25T11:01:10', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'b04e650b-be46-41da-b2f7-461dfb3d86af' User entered 'No (N)'	System	25 Sep 2020 15:01:16
	System	25 Sep 2020 15:01:16

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-25T11:01:14', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'b04e650b-be46-41da-b2f7-461dfb3d86af' User entered '25 Sep 2020 11:01'	System	25 Sep 2020 15:01:16
	System	25 Sep 2020 15:01:16

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '24 Sep 2020 12:51'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 2'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:45:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:45:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:45:43

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:45:43

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 3'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:45:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-26T14:24:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '358bd18e-dc4c-46c5-93ac-35faa4899bf7' User entered 'Yes (Y)'	System	26 Sep 2020 18:24:20
	System	26 Sep 2020 18:24:20

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:45:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-26T14:24:06', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '358bd18e-dc4c-46c5-93ac-35faa4899bf7' User entered '98.3'	System	26 Sep 2020 18:24:20
	System	26 Sep 2020 18:24:20

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-26T14:24:09', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '358bd18e-dc4c-46c5-93ac-35faa4899bf7' User entered 'No (N)'	System	26 Sep 2020 18:24:20
	System	26 Sep 2020 18:24:20

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-26T14:24:16', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '358bd18e-dc4c-46c5-93ac-35faa4899bf7' User entered '26 Sep 2020 14:24'	System	26 Sep 2020 18:24:20
	System	26 Sep 2020 18:24:20

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 4'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:45:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-27T20:10:17', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '2a13b76a-ff32-4da2-bca6-e4e31a66afc1' User entered 'Yes (Y)'	System	28 Sep 2020 00:10:33
	System	28 Sep 2020 00:10:33

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:45:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-27T20:10:23', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '2a13b76a-ff32-4da2-bca6-e4e31a66afc1' User entered '98.0'	System	28 Sep 2020 00:10:33
	System	28 Sep 2020 00:10:33

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-27T20:10:26', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '2a13b76a-ff32-4da2-bca6-e4e31a66afc1' User entered 'No (N)'	System	28 Sep 2020 00:10:33
	System	28 Sep 2020 00:10:33

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-27T20:10:30', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '2a13b76a-ff32-4da2-bca6-e4e31a66afc1' User entered '27 Sep 2020 20:10'	System	28 Sep 2020 00:10:33
	System	28 Sep 2020 00:10:33

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 5'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:45:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-28T20:04:28', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'eb2fbc83-ec42-4071-8b4e-9605f9a42fe5' User entered 'Yes (Y)'	System	29 Sep 2020 00:04:43
	System	29 Sep 2020 00:04:43

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:45:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-28T20:04:34', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'eb2fbc83-ec42-4071-8b4e-9605f9a42fe5' User entered '98.0'	System	29 Sep 2020 00:04:43
	System	29 Sep 2020 00:04:43

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-28T20:04:37', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'eb2fbc83-ec42-4071-8b4e-9605f9a42fe5'	System	29 Sep 2020 00:04:43
User entered 'No (N)'	System	29 Sep 2020 00:04:43

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-28T20:04:41', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'eb2fbc83-ec42-4071-8b4e-9605f9a42fe5' User entered '28 Sep 2020 20:04'	System	29 Sep 2020 00:04:43
	System	29 Sep 2020 00:04:43

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 6'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:45:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T07:08:46', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'c99ca9dc-c7a2-4ed9-9731-a04100e67bb5' User entered 'Yes (Y)'	System	30 Sep 2020 11:09:17
	System	30 Sep 2020 11:09:17

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:45:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T07:09:08', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'c99ca9dc-c7a2-4ed9-9731-a04100e67bb5' User entered '98.0'	System	30 Sep 2020 11:09:17
	System	30 Sep 2020 11:09:17

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T07:09:11', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'c99ca9dc-c7a2-4ed9-9731-a04100e67bb5'	System	30 Sep 2020 11:09:17
User entered 'No (N)'	System	30 Sep 2020 11:09:17

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T07:09:15', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'c99ca9dc-c7a2-4ed9-9731-a04100e67bb5' User entered '30 Sep 2020 07:09'	System	30 Sep 2020 11:09:17
	System	30 Sep 2020 11:09:17

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 7'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:45:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T12:00:17', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'a70598a4-6c01-4bec-94c3-5b9dfb4d74e5' User entered 'Yes (Y)'	System	30 Sep 2020 16:00:42
	System	30 Sep 2020 16:00:42

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:45:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T12:00:28', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'a70598a4-6c01-4bec-94c3-5b9dfb4d74e5' User entered '98.3'	System	30 Sep 2020 16:00:42
	System	30 Sep 2020 16:00:42

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T12:00:30', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'a70598a4-6c01-4bec-94c3-5b9dfb4d74e5' User entered 'No (N)'	System	30 Sep 2020 16:00:42
	System	30 Sep 2020 16:00:42

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T12:00:34', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'a70598a4-6c01-4bec-94c3-5b9dfb4d74e5' User entered '30 Sep 2020 12:00'	System	30 Sep 2020 16:00:42
	System	30 Sep 2020 16:00:42

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-24T09:37:38', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'b687308e-85b4-4ebb-91d0-7765ecafa250'	System	24 Sep 2020 13:52:39
User entered 'None (1)'	System	24 Sep 2020 13:52:39

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-24T09:37:40', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'b687308e-85b4-4ebb-91d0-7765ecafa250' User entered 'No (N)'	System	24 Sep 2020 13:52:39
	System	24 Sep 2020 13:52:39

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-24T09:37:42', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'b687308e-85b4-4ebb-91d0-7765ecafa250' User entered 'No (N)'	System	24 Sep 2020 13:52:39
	System	24 Sep 2020 13:52:39

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-24T09:52:32', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'b687308e-85b4-4ebb-91d0-7765ecafa250'	System	24 Sep 2020 13:52:39
User entered 'None (1)'	System	24 Sep 2020 13:52:39

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-24T09:52:35', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'b687308e-85b4-4ebb-91d0-7765ecafa250' User entered '24 Sep 2020 09:52'	System	24 Sep 2020 13:52:39
	System	24 Sep 2020 13:52:39

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '24 Sep 2020 09:26'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '24 Sep 2020 11:56'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-25T11:00:33', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '343ca60e-0fc4-4f11-a8e7-c33c499bbe27'	System	25 Sep 2020 15:00:56
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 15:00:56

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-25T11:00:36', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '343ca60e-0fc4-4f11-a8e7-c33c499bbe27'	System	25 Sep 2020 15:00:56
User entered 'No (N)'	System	25 Sep 2020 15:00:56

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-25T11:00:45', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '343ca60e-0fc4-4f11-a8e7-c33c499bbe27'	System	25 Sep 2020 15:00:56
User entered 'No (N)'	System	25 Sep 2020 15:00:56

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-25T11:00:49', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '343ca60e-0fc4-4f11-a8e7-c33c499bbe27'	System	25 Sep 2020 15:00:56
User entered 'None (1)'	System	25 Sep 2020 15:00:56

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-25T11:00:55', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '343ca60e-0fc4-4f11-a8e7-c33c499bbe27' User entered '25 Sep 2020 11:00'	System	25 Sep 2020 15:00:56
	System	25 Sep 2020 15:00:56

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '24 Sep 2020 12:51'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 2'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:45:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 3'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-26T14:24:53', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '2196d021-6434-408d-8bf7-5cbff26c3a66'	System	26 Sep 2020 18:25:19
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 18:25:19

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:45:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-26T14:24:56', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '2196d021-6434-408d-8bf7-5cbff26c3a66'	System	26 Sep 2020 18:25:19
User entered 'Yes (Y)'	System	26 Sep 2020 18:25:19

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-26T14:25:02', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '2196d021-6434-408d-8bf7-5cbff26c3a66' User entered '2'	System	26 Sep 2020 18:25:19
	System	26 Sep 2020 18:25:19

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-26T14:25:06', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '2196d021-6434-408d-8bf7-5cbff26c3a66'	System	26 Sep 2020 18:25:19
User entered 'Yes (Y)'	System	26 Sep 2020 18:25:19

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-26T14:25:09', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '2196d021-6434-408d-8bf7-5cbff26c3a66' User entered '2'	System	26 Sep 2020 18:25:19
	System	26 Sep 2020 18:25:19

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-26T14:25:11', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '2196d021-6434-408d-8bf7-5cbff26c3a66'	System	26 Sep 2020 18:25:19
User entered 'None (1)'	System	26 Sep 2020 18:25:19

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-26T14:25:17', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '2196d021-6434-408d-8bf7-5cbff26c3a66' User entered '26 Sep 2020 14:25'	System	26 Sep 2020 18:25:19
	System	26 Sep 2020 18:25:19

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 4'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-27T20:11:08', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'fc7cfe6a-e37a-4e84-9d39-09f3672b45a1' User entered 'None (1)'	System	28 Sep 2020 00:11:34
	System	28 Sep 2020 00:11:34

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:45:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-27T20:11:11', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'fc7cfe6a-e37a-4e84-9d39-09f3672b45a1' User entered 'Yes (Y)'	System	28 Sep 2020 00:11:34
	System	28 Sep 2020 00:11:34

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-27T20:11:15', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'fc7cfe6a-e37a-4e84-9d39-09f3672b45a1' User entered '2'	System	28 Sep 2020 00:11:34
	System	28 Sep 2020 00:11:34

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-27T20:11:20', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'fc7cfe6a-e37a-4e84-9d39-09f3672b45a1' User entered 'No (N)'	System	28 Sep 2020 00:11:34
	System	28 Sep 2020 00:11:34

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-27T20:11:28', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'fc7cfe6a-e37a-4e84-9d39-09f3672b45a1' User entered 'None (1)'	System	28 Sep 2020 00:11:34
	System	28 Sep 2020 00:11:34

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-27T20:11:31', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'fc7cfe6a-e37a-4e84-9d39-09f3672b45a1' User entered '27 Sep 2020 20:11'	System	28 Sep 2020 00:11:34
	System	28 Sep 2020 00:11:34

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 5'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-28T20:05:04', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '35a5d196-7efd-46e8-84a8-c3a335d0b3f7' User entered 'None (1)'	System	29 Sep 2020 00:05:17
	System	29 Sep 2020 00:05:17

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:45:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-28T20:05:06', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '35a5d196-7efd-46e8-84a8-c3a335d0b3f7' User entered 'No (N)'	System	29 Sep 2020 00:05:17
	System	29 Sep 2020 00:05:17

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-28T20:05:08', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '35a5d196-7efd-46e8-84a8-c3a335d0b3f7' User entered 'No (N)'	System	29 Sep 2020 00:05:17
	System	29 Sep 2020 00:05:17

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-28T20:05:10', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '35a5d196-7efd-46e8-84a8-c3a335d0b3f7' User entered 'None (1)'	System	29 Sep 2020 00:05:17
	System	29 Sep 2020 00:05:17

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-28T20:05:13', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '35a5d196-7efd-46e8-84a8-c3a335d0b3f7' User entered '28 Sep 2020 20:05'	System	29 Sep 2020 00:05:17
	System	29 Sep 2020 00:05:17

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 6'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T07:09:22', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ad2963b8-0288-4c69-bf71-bea0080540cc' User entered 'None (1)'	System	30 Sep 2020 11:09:39
	System	30 Sep 2020 11:09:39

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:45:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T07:09:25', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ad2963b8-0288-4c69-bf71-bea0080540cc' User entered 'No (N)'	System	30 Sep 2020 11:09:39
	System	30 Sep 2020 11:09:39

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T07:09:27', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ad2963b8-0288-4c69-bf71-bea0080540cc' User entered 'No (N)'	System	30 Sep 2020 11:09:39
	System	30 Sep 2020 11:09:39

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T07:09:30', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ad2963b8-0288-4c69-bf71-bea0080540cc' User entered 'None (1)'	System	30 Sep 2020 11:09:39
	System	30 Sep 2020 11:09:39

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T07:09:34', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ad2963b8-0288-4c69-bf71-bea0080540cc' User entered '30 Sep 2020 07:09'	System	30 Sep 2020 11:09:39
	System	30 Sep 2020 11:09:39

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 7'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T12:00:41', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '8b2a52e3-368f-45c4-894a-dd567a7a3f67'	System	30 Sep 2020 16:01:15
User entered 'None (1)'	System	30 Sep 2020 16:01:15

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:45:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T12:00:43', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '8b2a52e3-368f-45c4-894a-dd567a7a3f67' User entered 'No (N)'	System	30 Sep 2020 16:01:15
	System	30 Sep 2020 16:01:15

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T12:00:45', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '8b2a52e3-368f-45c4-894a-dd567a7a3f67'	System	30 Sep 2020 16:01:15
User entered 'No (N)'	System	30 Sep 2020 16:01:15

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T12:00:47', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '8b2a52e3-368f-45c4-894a-dd567a7a3f67'	System	30 Sep 2020 16:01:15
User entered 'None (1)'	System	30 Sep 2020 16:01:15

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:45:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T12:00:50', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '8b2a52e3-368f-45c4-894a-dd567a7a3f67' User entered '30 Sep 2020 12:00'	System	30 Sep 2020 16:01:15
	System	30 Sep 2020 16:01:15

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-24T09:52:46', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '4f155321-1d98-44ec-a442-2fd1bec41f28' User entered 'None (0)'	System	24 Sep 2020 13:53:02
	System	24 Sep 2020 13:53:02

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-24T09:52:48', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '4f155321-1d98-44ec-a442-2fd1bec41f28' User entered 'None (0)'	System	24 Sep 2020 13:53:02
	System	24 Sep 2020 13:53:02

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-24T09:52:49', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '4f155321-1d98-44ec-a442-2fd1bec41f28' User entered 'None (0)'	System	24 Sep 2020 13:53:02
	System	24 Sep 2020 13:53:02

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-24T09:52:51', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '4f155321-1d98-44ec-a442-2fd1bec41f28' User entered 'None (0)'	System	24 Sep 2020 13:53:02
	System	24 Sep 2020 13:53:02

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-24T09:52:52', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '4f155321-1d98-44ec-a442-2fd1bec41f28' User entered 'None (0)'	System	24 Sep 2020 13:53:02
	System	24 Sep 2020 13:53:02

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-24T09:52:54', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '4f155321-1d98-44ec-a442-2fd1bec41f28' User entered 'None (0)'	System	24 Sep 2020 13:53:02
	System	24 Sep 2020 13:53:02

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-24T09:52:55', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '4f155321-1d98-44ec-a442-2fd1bec41f28' User entered 'No (N)'	System	24 Sep 2020 13:53:02
	System	24 Sep 2020 13:53:02

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-24T09:52:59', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '4f155321-1d98-44ec-a442-2fd1bec41f28' User entered '24 Sep 2020 09:52'	System	24 Sep 2020 13:53:02
	System	24 Sep 2020 13:53:02

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '24 Sep 2020 09:26'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '24 Sep 2020 11:56'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-25T11:01:18', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'f16325db-470c-4021-a4d0-dcc21c13d627' User entered 'None (0)'	System	25 Sep 2020 15:01:39
	System	25 Sep 2020 15:01:39

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-25T11:01:23', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'f16325db-470c-4021-a4d0-dcc21c13d627' User entered 'None (0)'	System	25 Sep 2020 15:01:39
	System	25 Sep 2020 15:01:39

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-25T11:01:25', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'f16325db-470c-4021-a4d0-dcc21c13d627' User entered 'None (0)'	System	25 Sep 2020 15:01:39
	System	25 Sep 2020 15:01:39

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-25T11:01:26', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'f16325db-470c-4021-a4d0-dcc21c13d627' User entered 'None (0)'	System	25 Sep 2020 15:01:39
	System	25 Sep 2020 15:01:39

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-25T11:01:28', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'f16325db-470c-4021-a4d0-dcc21c13d627' User entered 'None (0)'	System	25 Sep 2020 15:01:39
	System	25 Sep 2020 15:01:39

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-25T11:01:29', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'f16325db-470c-4021-a4d0-dcc21c13d627' User entered 'None (0)'	System	25 Sep 2020 15:01:39
	System	25 Sep 2020 15:01:39

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-25T11:01:32', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'f16325db-470c-4021-a4d0-dcc21c13d627' User entered 'No (N)'	System	25 Sep 2020 15:01:39
	System	25 Sep 2020 15:01:39

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-25T11:01:35', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'f16325db-470c-4021-a4d0-dcc21c13d627' User entered '25 Sep 2020 11:01'	System	25 Sep 2020 15:01:39
	System	25 Sep 2020 15:01:39

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '24 Sep 2020 12:51'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 2'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 3'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-26T14:24:21', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '7739fe85-a692-4c5e-b603-fe36e7a6bd70' User entered 'None (0)'	System	26 Sep 2020 18:24:44
	System	26 Sep 2020 18:24:44

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-26T14:24:22', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '7739fe85-a692-4c5e-b603-fe36e7a6bd70' User entered 'None (0)'	System	26 Sep 2020 18:24:44
	System	26 Sep 2020 18:24:44

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-26T14:24:25', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '7739fe85-a692-4c5e-b603-fe36e7a6bd70' User entered 'None (0)'	System	26 Sep 2020 18:24:44
	System	26 Sep 2020 18:24:44

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-26T14:24:28', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '7739fe85-a692-4c5e-b603-fe36e7a6bd70' User entered 'None (0)'	System	26 Sep 2020 18:24:44
	System	26 Sep 2020 18:24:44

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-26T14:24:30', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '7739fe85-a692-4c5e-b603-fe36e7a6bd70' User entered 'None (0)'	System	26 Sep 2020 18:24:44
	System	26 Sep 2020 18:24:44

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-26T14:24:32', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '7739fe85-a692-4c5e-b603-fe36e7a6bd70' User entered 'None (0)'	System	26 Sep 2020 18:24:44
	System	26 Sep 2020 18:24:44

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-26T14:24:35', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '7739fe85-a692-4c5e-b603-fe36e7a6bd70' User entered 'No (N)'	System	26 Sep 2020 18:24:44
	System	26 Sep 2020 18:24:44

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-26T14:24:42', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '7739fe85-a692-4c5e-b603-fe36e7a6bd70' User entered '26 Sep 2020 14:24'	System	26 Sep 2020 18:24:44
	System	26 Sep 2020 18:24:44

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 4'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-27T20:10:33', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ddcd92e6-bdbb-4345-8f3b-57e53be9fbfa' User entered 'None (0)'	System	28 Sep 2020 00:10:54
	System	28 Sep 2020 00:10:54

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-27T20:10:35', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ddcd92e6-bdbb-4345-8f3b-57e53be9fbfa' User entered 'None (0)'	System	28 Sep 2020 00:10:54
	System	28 Sep 2020 00:10:54

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-27T20:10:37', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ddcd92e6-bdbb-4345-8f3b-57e53be9fbfa' User entered 'None (0)'	System	28 Sep 2020 00:10:54
	System	28 Sep 2020 00:10:54

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-27T20:10:39', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ddcd92e6-bdbb-4345-8f3b-57e53be9fbfa' User entered 'None (0)'	System	28 Sep 2020 00:10:54
	System	28 Sep 2020 00:10:54

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-27T20:10:41', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ddcd92e6-bdbb-4345-8f3b-57e53be9fbfa' User entered 'None (0)'	System	28 Sep 2020 00:10:54
	System	28 Sep 2020 00:10:54

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-27T20:10:42', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ddcd92e6-bdbb-4345-8f3b-57e53be9fbfa' User entered 'None (0)'	System	28 Sep 2020 00:10:54
	System	28 Sep 2020 00:10:54

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-27T20:10:46', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ddcd92e6-bdbb-4345-8f3b-57e53be9fbfa' User entered 'No (N)'	System	28 Sep 2020 00:10:54
	System	28 Sep 2020 00:10:54

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-27T20:10:51', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ddcd92e6-bdbb-4345-8f3b-57e53be9fbfa' User entered '27 Sep 2020 20:10'	System	28 Sep 2020 00:10:54
	System	28 Sep 2020 00:10:54

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 5'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-28T20:04:44', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'e067d0a9-bc69-477f-b26a-819c58262efb' User entered 'None (0)'	System	29 Sep 2020 00:04:59
	System	29 Sep 2020 00:04:59

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-28T20:04:46', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'e067d0a9-bc69-477f-b26a-819c58262efb' User entered 'None (0)'	System	29 Sep 2020 00:04:59
	System	29 Sep 2020 00:04:59

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-28T20:04:48', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'e067d0a9-bc69-477f-b26a-819c58262efb' User entered 'None (0)'	System	29 Sep 2020 00:04:59
	System	29 Sep 2020 00:04:59

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-28T20:04:49', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'e067d0a9-bc69-477f-b26a-819c58262efb' User entered 'None (0)'	System	29 Sep 2020 00:04:59
	System	29 Sep 2020 00:04:59

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-28T20:04:51', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'e067d0a9-bc69-477f-b26a-819c58262efb' User entered 'None (0)'	System	29 Sep 2020 00:04:59
	System	29 Sep 2020 00:04:59

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-28T20:04:52', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'e067d0a9-bc69-477f-b26a-819c58262efb' User entered 'None (0)'	System	29 Sep 2020 00:04:59
	System	29 Sep 2020 00:04:59

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-28T20:04:54', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'e067d0a9-bc69-477f-b26a-819c58262efb' User entered 'No (N)'	System	29 Sep 2020 00:04:59
	System	29 Sep 2020 00:04:59

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-28T20:04:58', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'e067d0a9-bc69-477f-b26a-819c58262efb' User entered '28 Sep 2020 20:04'	System	29 Sep 2020 00:04:59
	System	29 Sep 2020 00:04:59

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 6'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T07:09:39', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '95f9731c-a655-47ce-b445-3f19684aae00' User entered 'None (0)'	System	30 Sep 2020 11:09:52
	System	30 Sep 2020 11:09:52

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T07:09:41', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '95f9731c-a655-47ce-b445-3f19684aae00' User entered 'None (0)'	System	30 Sep 2020 11:09:52
	System	30 Sep 2020 11:09:52

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T07:09:42', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '95f9731c-a655-47ce-b445-3f19684aae00' User entered 'None (0)'	System	30 Sep 2020 11:09:52
	System	30 Sep 2020 11:09:52

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T07:09:44', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '95f9731c-a655-47ce-b445-3f19684aae00' User entered 'None (0)'	System	30 Sep 2020 11:09:52
	System	30 Sep 2020 11:09:52

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T07:09:45', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '95f9731c-a655-47ce-b445-3f19684aae00' User entered 'None (0)'	System	30 Sep 2020 11:09:52
	System	30 Sep 2020 11:09:52

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T07:09:47', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '95f9731c-a655-47ce-b445-3f19684aae00' User entered 'None (0)'	System	30 Sep 2020 11:09:52
	System	30 Sep 2020 11:09:52

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T07:09:48', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '95f9731c-a655-47ce-b445-3f19684aae00' User entered 'No (N)'	System	30 Sep 2020 11:09:52
	System	30 Sep 2020 11:09:52

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T07:09:51', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '95f9731c-a655-47ce-b445-3f19684aae00' User entered '30 Sep 2020 07:09'	System	30 Sep 2020 11:09:52
	System	30 Sep 2020 11:09:52

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Sep 2020 13:26:40
User entered 'Day 7'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T12:39:39', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ef8d6638-e2ce-4f09-b15c-a4855e8cba21' User entered 'None (0)'	System	30 Sep 2020 16:39:55
	System	30 Sep 2020 16:39:55

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T12:39:41', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ef8d6638-e2ce-4f09-b15c-a4855e8cba21' User entered 'None (0)'	System	30 Sep 2020 16:39:55
	System	30 Sep 2020 16:39:55

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T12:39:42', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ef8d6638-e2ce-4f09-b15c-a4855e8cba21' User entered 'None (0)'	System	30 Sep 2020 16:39:55
	System	30 Sep 2020 16:39:55

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T12:39:43', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ef8d6638-e2ce-4f09-b15c-a4855e8cba21' User entered 'None (0)'	System	30 Sep 2020 16:39:55
	System	30 Sep 2020 16:39:55

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T12:39:45', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ef8d6638-e2ce-4f09-b15c-a4855e8cba21' User entered 'None (0)'	System	30 Sep 2020 16:39:55
	System	30 Sep 2020 16:39:55

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T12:39:46', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ef8d6638-e2ce-4f09-b15c-a4855e8cba21' User entered 'None (0)'	System	30 Sep 2020 16:39:55
	System	30 Sep 2020 16:39:55

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T12:39:47', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ef8d6638-e2ce-4f09-b15c-a4855e8cba21' User entered 'No (N)'	System	30 Sep 2020 16:39:55
	System	30 Sep 2020 16:39:55

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-09-30T12:39:50', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ef8d6638-e2ce-4f09-b15c-a4855e8cba21' User entered '30 Sep 2020 12:39'	System	30 Sep 2020 16:39:55
	System	30 Sep 2020 16:39:55

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 13:26:40

US3482023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:45:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 13:26:40

US3482023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:06:57

US3482023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:52:30
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 14:06:57

US3482023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:06:57

US3482023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:06:57

US3482023

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
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	01 Oct 2020 14:07:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 14:07:05
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 14:07:01
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 14:07:01

US3482023

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered '1'	System	01 Oct 2020 14:07:05
User entered empty.	System	01 Oct 2020 14:07:01

US3482023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:45:32

US3482023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:52:39
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 12:45:32

US3482023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:45:32

US3482023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:45:32

US3482023

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 12:39:04

US3482023

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered 'I'	System	21 Oct 2020 12:39:04

US3482023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 14:43:22

US3482023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 14:43:22

US3482023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 14:43:22

US3482023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 14:43:22

US3482023

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 12:39:17

US3482023

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:29
User entered 'I'	System	21 Oct 2020 12:39:17

US3482023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 12:39:28

US3482023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 12:39:28

US3482023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

[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 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 12:39:28

US3482023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered 'VISIT3'	System	21 Oct 2020 12:39:28

US3482023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 12:39:32

US3482023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 12:39:32

US3482023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 12:39:32

US3482023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered empty.	System	21 Oct 2020 12:39:32

US3482023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 12:39:32

US3482023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 12:39:32

US3482023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 12:39:32

US3482023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 12:39:32

US3482023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered empty.	System	21 Oct 2020 12:39:32

US3482023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 12:39:32

US3482023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered empty.	System	21 Oct 2020 12:39:32

US3482023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 12:39:32

US3482023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered empty.	System	21 Oct 2020 12:39:32

US3482023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 12:39:32

US3482023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered empty.	System	21 Oct 2020 12:39:32

US3482023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56

US3482023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56

US3482023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:45:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 12:39:35

US3482023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:45:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 12:39:35

US3482023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:45:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 12:39:44

US3482023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:45:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 12:39:44

US3482023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:45:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered '08:20'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 12:39:44

US3482023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:45:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered '21 Oct 2020 08:20'	System	21 Oct 2020 12:39:44

US3482023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:07:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 12:39:47

US3482023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered 'I'	System	21 Oct 2020 12:39:47

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 64'	System	24 Aug 2020 14:10:45

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-10-27T10:22:32', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'a2be9ec0-54ab-45f2-bb99-f2d5fa6e410a' User entered 'No (N)'	System	27 Oct 2020 14:22:46
	System	27 Oct 2020 14:22:46

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Have you been exposed to someone with 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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-10-27T10:22:37', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'a2be9ec0-54ab-45f2-bb99-f2d5fa6e410a'	System	27 Oct 2020 14:22:46
User entered 'No (N)'	System	27 Oct 2020 14:22:46

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-10-27T10:22:44', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'a2be9ec0-54ab-45f2-bb99-f2d5fa6e410a' User entered '27 Oct 2020 10:22:44'	System	27 Oct 2020 14:22:46
	System	27 Oct 2020 14:22:46

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 14:10:45

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 71'	System	24 Aug 2020 14:10:45

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-10-31T00:01:33', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'edcc64a4-e148-437a-9ea7-c3e3fe41f269'	System	31 Oct 2020 04:01:50
User entered 'No (N)'	System	31 Oct 2020 04:01:50

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Have you been exposed to someone with 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 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-10-31T00:01:37', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'edcc64a4-e148-437a-9ea7-c3e3fe41f269'	System	31 Oct 2020 04:01:50
User entered 'No (N)'	System	31 Oct 2020 04:01:50

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-10-31T00:01:42', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'edcc64a4-e148-437a-9ea7-c3e3fe41f269' User entered '31 Oct 2020 00:01:42'	System	31 Oct 2020 04:01:50
	System	31 Oct 2020 04:01:50

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 14:10:45

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:42:43
Data entry locked.	System	24 Aug 2020 14:10:45
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39
Data entry locked.	System	24 Aug 2020 14:10:45
User entered 'Day 78'	System	24 Aug 2020 14:10:45

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39
Data entry locked.	System	24 Aug 2020 14:10:45
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 14:10:45

US3482023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:35:39
Data entry locked.	System	24 Aug 2020 14:10:45
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 14:10:45

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-11-19T13:03:03', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '5d1b8c44-8897-46fb-bf15-66c6db4e7e1e' User entered 'No (N)'	System	19 Nov 2020 18:03:14
	System	19 Nov 2020 18:03:14

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Have you been exposed to someone with 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 (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-11-19T13:03:06', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '5d1b8c44-8897-46fb-bf15-66c6db4e7e1e'	System	19 Nov 2020 18:03:14
User entered 'No (N)'	System	19 Nov 2020 18:03:14

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-11-19T13:03:09', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '5d1b8c44-8897-46fb-bf15-66c6db4e7e1e' User entered '19 Nov 2020 13:03:09'	System	19 Nov 2020 18:03:14
	System	19 Nov 2020 18:03:14

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-11-25T00:01:21', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '7eb931db-6dc2-4161-8249-120d9d9d9d9d' User entered 'No (N)'	System	25 Nov 2020 05:01:37
	System	25 Nov 2020 05:01:37

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Have you been exposed to someone with 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 (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-11-25T00:01:24', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '7eb931db-6dc2-4161-8249-120d9d9d9d9d' User entered 'No (N)'	System	25 Nov 2020 05:01:37

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-11-25T00:01:30', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '7eb931db-6dc2-4161-8249-120d9dfeab3' User entered '25 Nov 2020 00:01:30'	System	25 Nov 2020 05:01:37
	System	25 Nov 2020 05:01:37

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-12-03T23:20:18', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1c95ea9d-0414-47a0-ad0c-60bae394bfe9' User entered 'No (N)'	System	04 Dec 2020 04:20:28
	System	04 Dec 2020 04:20:28

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Have you been exposed to someone with 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 (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-12-03T23:20:21', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1c95ea9d-0414-47a0-ad0c-60bae394bfe9' User entered 'No (N)'	System	04 Dec 2020 04:20:28
	System	04 Dec 2020 04:20:28

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-12-03T23:20:26', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '1c95ea9d-0414-47a0-ad0c-60bae394bfe9' User entered '03 Dec 2020 23:20:26'	System	04 Dec 2020 04:20:28
	System	04 Dec 2020 04:20:28

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-12-18T17:59:41', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '726c3300-56c9-4e51-828c-76b49b4f1401' User entered 'No (N)'	System	19 Dec 2020 00:31:02
	System	19 Dec 2020 00:31:02

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Have you been exposed to someone with 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 (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-12-18T17:59:43', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '726c3300-56c9-4e51-828c-76b49b4f1401' User entered 'No (N)'	System	19 Dec 2020 00:31:02
	System	19 Dec 2020 00:31:02

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-12-18T17:59:47', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '726c3300-56c9-4e51-828c-76b49b4f1401'	System	19 Dec 2020 00:31:02
User entered '18 Dec 2020 17:59:47'	System	19 Dec 2020 00:31:02

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-12-23T13:08:05', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '6419a096-f49d-44ae-be7a-dac656d2eab7' User entered 'No (N)'	System	23 Dec 2020 18:08:13
	System	23 Dec 2020 18:08:13

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Have you been exposed to someone with 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 (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-12-23T13:08:07', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '6419a096-f49d-44ae-be7a-dac656d2eab7' User entered 'No (N)'	System	23 Dec 2020 18:08:13
	System	23 Dec 2020 18:08:13

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63E94BDA-083D-48FE-BAFB-D2AA7C64CAE0)', Time: '2020-12-23T13:08:11', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '6419a096-f49d-44ae-be7a-dac656d2eab7' User entered '23 Dec 2020 13:08:11'	System	23 Dec 2020 18:08:13
	System	23 Dec 2020 18:08:13

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-01-06T12:47:21', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'fb9b5eef-7c70-4a6a-9a98-d2bd9910727c'	System	06 Jan 2021 17:47:46
User entered 'No (N)'	System	06 Jan 2021 17:47:46

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Have you been exposed to someone with 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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-01-06T12:47:28', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'fb9b5eef-7c70-4a6a-9a98-d2bd9910727c'	System	06 Jan 2021 17:47:46
User entered 'Yes (Y)'	System	06 Jan 2021 17:47:46

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-01-06T12:47:30', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'fb9b5eef-7c70-4a6a-9a98-d2bd9910727c'	System	06 Jan 2021 17:47:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Jan 2021 17:47:46

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-01-06T12:47:36', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'fb9b5eef-7c70-4a6a-9a98-d2bd9910727c' User entered '06 Jan 2021 12:47:36'	System	06 Jan 2021 17:47:46
	System	06 Jan 2021 17:47:46

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-01-13T02:02:43', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'bea398f6-e72d-4f8d-8cdc-093491b7c70d' User entered 'No (N)'	System	13 Jan 2021 07:02:53

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Have you been exposed to someone with 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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-01-13T02:02:46', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'bea398f6-e72d-4f8d-8cdc-093491b7c70d'	System	13 Jan 2021 07:02:53
User entered 'No (N)'	System	13 Jan 2021 07:02:53

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-01-13T02:02:51', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'bea398f6-e72d-4f8d-8cdc-093491b7c70d' User entered '13 Jan 2021 02:02:51'	System	13 Jan 2021 07:02:53
	System	13 Jan 2021 07:02:53

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-01-20T20:28:34', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'dd4a4a1d-94f5-4f8e-8751-ca6acbdce853' User entered 'No (N)'	System	21 Jan 2021 01:28:45
	System	21 Jan 2021 01:28:45

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Have you been exposed to someone with 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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-01-20T20:28:37', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'dd4a4a1d-94f5-4f8e-8751-ca6acbdce853' User entered 'No (N)'	System	21 Jan 2021 01:28:45

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-01-20T20:28:42', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'dd4a4a1d-94f5-4f8e-8751-ca6acbdce853' User entered '20 Jan 2021 20:28:42'	System	21 Jan 2021 01:28:45
	System	21 Jan 2021 01:28:45

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-01-28T09:20:37', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '8a950ceb-385a-4ecf-8d61-f468de3606a1' User entered 'No (N)'	System	28 Jan 2021 14:21:18
	System	28 Jan 2021 14:21:18

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Have you been exposed to someone with 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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-01-28T09:20:50', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '8a950ceb-385a-4ecf-8d61-f468de3606a1'	System	28 Jan 2021 14:21:18
User entered 'Yes (Y)'	System	28 Jan 2021 14:21:18

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-01-28T09:20:58', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '8a950ceb-385a-4ecf-8d61-f468de3606a1'	System	28 Jan 2021 14:21:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Jan 2021 14:21:18

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-01-28T09:21:03', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '8a950ceb-385a-4ecf-8d61-f468de3606a1' User entered '28 Jan 2021 09:21:03'	System	28 Jan 2021 14:21:18
	System	28 Jan 2021 14:21:18

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-02-04T22:09:48', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '0efba37c-4bd4-4b17-8025-0027a3c6990b' User entered 'No (N)'	System	05 Feb 2021 03:10:02
	System	05 Feb 2021 03:10:02

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Have you been exposed to someone with 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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-02-04T22:09:53', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '0efba37c-4bd4-4b17-8025-0027a3c6990b' User entered 'No (N)'	System	05 Feb 2021 03:10:02

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-02-04T22:09:59', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '0efba37c-4bd4-4b17-8025-0027a3c6990b' User entered '04 Feb 2021 22:09:59'	System	05 Feb 2021 03:10:02

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-02-10T22:58:57', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'd49604a7-9677-4dff-8b5d-13e22e60ad67'	System	11 Feb 2021 03:59:25
User entered 'Yes (Y)'	System	11 Feb 2021 03:59:25

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Have you been exposed to someone with 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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-02-10T22:59:01', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'd49604a7-9677-4dff-8b5d-13e22e60ad67'	System	11 Feb 2021 03:59:25
User entered 'No (N)'	System	11 Feb 2021 03:59:25

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-02-10T22:59:06', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'd49604a7-9677-4dff-8b5d-13e22e60ad67'	System	11 Feb 2021 03:59:25
User entered 'No (N)'	System	11 Feb 2021 03:59:25

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-02-10T22:59:15', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'd49604a7-9677-4dff-8b5d-13e22e60ad67'	System	11 Feb 2021 03:59:25
User entered 'No (N)'	System	11 Feb 2021 03:59:25

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-02-10T22:59:23', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'd49604a7-9677-4dff-8b5d-13e22e60ad67'	System	11 Feb 2021 03:59:25
User entered '10 Feb 2021 22:59:23'	System	11 Feb 2021 03:59:25

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-02-17T18:07:09', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'abae98ee-e568-42fc-9473-46f37b7229b8' User entered 'No (N)'	System	24 Feb 2021 05:02:27
	System	24 Feb 2021 05:02:27

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Have you been exposed to someone with 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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-02-17T18:07:12', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'abae98ee-e568-42fc-9473-46f37b7229b8' User entered 'No (N)'	System	24 Feb 2021 05:02:27

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-02-17T18:07:20', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'abae98ee-e568-42fc-9473-46f37b7229b8' User entered '17 Feb 2021 18:07:20'	System	24 Feb 2021 05:02:27
	System	24 Feb 2021 05:02:27

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-02-24T00:01:24-05:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '813bff82-400f-494b-8190-e237fec3cff4'	System	24 Feb 2021 05:02:50
User entered 'No (N)'	System	24 Feb 2021 05:02:50

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Have you been exposed to someone with 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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-02-24T00:01:27-05:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '813bff82-400f-494b-8190-e237fec3cff4'	System	24 Feb 2021 05:02:50
User entered 'No (N)'	System	24 Feb 2021 05:02:50

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-02-24T00:01:31-05:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '813bff82-400f-494b-8190-e237fec3cff4' User entered '24 Feb 2021 05:01:31'	System	24 Feb 2021 05:02:50
	System	24 Feb 2021 05:02:50

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-03-03T00:02:32-05:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'fdcc38df-42d2-488b-bf72-03b6ee19af33'	System	03 Mar 2021 05:04:33
User entered 'No (N)'	System	03 Mar 2021 05:04:33

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Have you been exposed to someone with 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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-03-03T00:02:35-05:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'fdcc38df-42d2-488b-bf72-03b6ee19af33'	System	03 Mar 2021 05:04:33
User entered 'No (N)'	System	03 Mar 2021 05:04:33

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-03-03T00:02:42-05:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'fdcc38df-42d2-488b-bf72-03b6ee19af33'	System	03 Mar 2021 05:04:33
User entered '03 Mar 2021 00:02:42'	System	03 Mar 2021 05:04:33

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-03-11T14:02:57-05:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '05abc7c7-c464-49e2-944e-6e57972a24b3'	System	11 Mar 2021 19:03:08
User entered 'No (N)'	System	11 Mar 2021 19:03:08

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Have you been exposed to someone with 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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-03-11T14:02:59-05:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '05abc7c7-c464-49e2-944e-6e57972a24b3'	System	11 Mar 2021 19:03:08
User entered 'No (N)'	System	11 Mar 2021 19:03:08

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-03-11T14:03:02-05:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '05abc7c7-c464-49e2-944e-6e57972a24b3' User entered '11 Mar 2021 14:03:02'	System	11 Mar 2021 19:03:08
	System	11 Mar 2021 19:03:08

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-03-18T12:22:38-04:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'd1dc71b5-b0d2-4a47-be7b-1f4ccb671ed2'	System	18 Mar 2021 16:22:48
User entered 'No (N)'	System	18 Mar 2021 16:22:48

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Have you been exposed to someone with 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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-03-18T12:22:41-04:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'd1dc71b5-b0d2-4a47-be7b-1f4ccb671ed2'	System	18 Mar 2021 16:22:48
User entered 'No (N)'	System	18 Mar 2021 16:22:48

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-03-18T12:22:44-04:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'd1dc71b5-b0d2-4a47-be7b-1f4ccb671ed2' User entered '18 Mar 2021 12:22:44'	System	18 Mar 2021 16:22:48
	System	18 Mar 2021 16:22:48

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-03-24T18:41:22-04:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '41d6b371-657d-4c38-af61-29c541f22dd0'	System	24 Mar 2021 22:41:31
User entered 'No (N)'	System	24 Mar 2021 22:41:31

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Have you been exposed to someone with 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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-03-24T18:41:24-04:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '41d6b371-657d-4c38-af61-29c541f22dd0'	System	24 Mar 2021 22:41:31
User entered 'No (N)'	System	24 Mar 2021 22:41:31

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-03-24T18:41:28-04:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '41d6b371-657d-4c38-af61-29c541f22dd0' User entered '24 Mar 2021 18:41:28'	System	24 Mar 2021 22:41:31
	System	24 Mar 2021 22:41:31

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-04-02T12:15:07-06:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ae40f99f-ac58-4d80-94cf-42826cb9ace7'	System	02 Apr 2021 18:15:14
User entered 'No (N)'	System	02 Apr 2021 18:15:14

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Have you been exposed to someone with 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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-04-02T12:15:09-06:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ae40f99f-ac58-4d80-94cf-42826cb9ace7'	System	02 Apr 2021 18:15:14
User entered 'No (N)'	System	02 Apr 2021 18:15:14

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-04-02T12:15:12-06:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'ae40f99f-ac58-4d80-94cf-42826cb9ace7'	System	02 Apr 2021 18:15:14
User entered '02 Apr 2021 12:15:12'	System	02 Apr 2021 18:15:14

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-04-09T14:02:33-04:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '6e6e00e5-af2f-4b02-8e8a-67cef84145f2'	System	09 Apr 2021 18:02:45
User entered 'No (N)'	System	09 Apr 2021 18:02:45

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Have you been exposed to someone with 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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-04-09T14:02:35-04:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '6e6e00e5-af2f-4b02-8e8a-67cef84145f2'	System	09 Apr 2021 18:02:45
User entered 'No (N)'	System	09 Apr 2021 18:02:45

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-04-09T14:02:38-04:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '6e6e00e5-af2f-4b02-8e8a-67cef84145f2'	System	09 Apr 2021 18:02:45
User entered '09 Apr 2021 14:02:38'	System	09 Apr 2021 18:02:45

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-04-14T20:18:14-04:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'd23212cb-e11e-4f4a-b36e-d4cf1887b4f0'	System	15 Apr 2021 00:18:22
User entered 'No (N)'	System	15 Apr 2021 00:18:22

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Have you been exposed to someone with 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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-04-14T20:18:16-04:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'd23212cb-e11e-4f4a-b36e-d4cf1887b4f0'	System	15 Apr 2021 00:18:22
User entered 'No (N)'	System	15 Apr 2021 00:18:22

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-04-14T20:18:19-04:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'd23212cb-e11e-4f4a-b36e-d4cf1887b4f0'	System	15 Apr 2021 00:18:22
User entered '14 Apr 2021 20:18:19'	System	15 Apr 2021 00:18:22

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-04-28T08:20:03-04:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'fd9e5a34-1f99-4f6c-8940-f88aaf015a92'	System	28 Apr 2021 23:29:01
User entered 'No (N)'	System	28 Apr 2021 23:29:01

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

Have you been exposed to someone with 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 (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-04-28T08:20:09-04:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'fd9e5a34-1f99-4f6c-8940-f88aaf015a92'	System	28 Apr 2021 23:29:01
User entered 'No (N)'	System	28 Apr 2021 23:29:01

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-04-28T08:20:11-04:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: 'fd9e5a34-1f99-4f6c-8940-f88aaf015a92'	System	28 Apr 2021 23:29:01
User entered '28 Apr 2021 08:20:11'	System	28 Apr 2021 23:29:01

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '26 Oct 2022 00:01'	System	19 Nov 2020 04:35:39

US3482023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:45:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:39
Amendment Manager: User entered '30 Oct 2022 23:59'	System	19 Nov 2020 04:35:39

US3482023

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:45:43

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-03-03T00:02:48-05:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '19449faf-dfc3-4c69-baa1-f109ada8973b'	System	03 Mar 2021 05:04:46
User entered 'Yes (Y)'	System	03 Mar 2021 05:04:46

US3482023

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:45:43

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-03-03T00:03:04-05:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '19449faf-dfc3-4c69-baa1-f109ada8973b'	System	03 Mar 2021 05:04:46
User entered 'No (N)'	System	03 Mar 2021 05:04:46

US3482023

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:45:43

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:10:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F2E3A3E-9D5B-4FDC-85CA-C6C42342B338)', Time: '2021-03-03T00:03:18-05:00', User OID: 'PatientReportedOutcome (US3482023)', ODM File OID: '19449faf-dfc3-4c69-baa1-f109ada8973b' User entered '03 Mar 2021 00:03:18'	System	03 Mar 2021 05:04:46
	System	03 Mar 2021 05:04:46

US3482023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:06:09

US3482023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:06:09

US3482023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:06:09

US3482023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:06:09

US3482023

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:06:20

US3482023

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:56
User entered 'I'	System	17 Nov 2020 15:06:20

US3482023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 21:49:24

US3482023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 21:49:24

US3482023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 21:49:24

US3482023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 21:49:24

US3482023

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:11:11

US3482023

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User entered 'I'	System	19 Jan 2021 20:11:11

US3482023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:11:20

US3482023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:11:20

US3482023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:11:20

US3482023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:11:20

US3482023

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:11:26

US3482023

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User entered '1'	System	19 Jan 2021 20:11:26

US3482023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:06:21

US3482023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:06:21

US3482023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:06:21

US3482023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:06:21

US3482023

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:06:26

US3482023

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User entered '1'	System	18 Feb 2021 19:06:26

US3482023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'Yes (Y)'	Lauren Hewitt (b) (4)	23 Mar 2021 14:36:46

US3482023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered '23 Mar 2021'	Lauren Hewitt (b) (4)	23 Mar 2021 14:36:46

US3482023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'Clinic (Clinic)'	Lauren Hewitt (b) (4)	23 Mar 2021 14:36:46

US3482023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User entered 'VISIT4'	System	23 Mar 2021 14:36:46

US3482023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'No (N)'	Mari Hart (b) (4)	31 Mar 2021 15:05:55

US3482023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered empty.	Mari Hart (b) (4)	31 Mar 2021 15:05:55

US3482023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered empty.	Mari Hart (b) (4)	31 Mar 2021 15:05:55

US3482023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User entered empty.	System	31 Mar 2021 15:05:55

US3482023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered empty.	Mari Hart (b) (4)	31 Mar 2021 15:05:55

US3482023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered empty.	Mari Hart (b) (4)	31 Mar 2021 15:05:55

US3482023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered empty.	Mari Hart (b) (4)	31 Mar 2021 15:05:55

US3482023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered empty.	Mari Hart (b) (4)	31 Mar 2021 15:05:55

US3482023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User entered empty.	System	31 Mar 2021 15:05:55

US3482023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered empty.	Mari Hart (b) (4)	31 Mar 2021 15:05:55

US3482023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User entered empty.	System	31 Mar 2021 15:05:55

US3482023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered empty.	Mari Hart (b) (4)	31 Mar 2021 15:05:55

US3482023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User entered empty.	System	31 Mar 2021 15:05:55

US3482023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered empty.	Mari Hart (b) (4)	31 Mar 2021 15:05:55

US3482023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User entered empty.	System	31 Mar 2021 15:05:55

US3482023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58

US3482023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:45:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58

US3482023

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:45:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'No (N)'	(b) (4) Lauren Hewitt (b) (4)	23 Mar 2021 14:36:52

US3482023

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:45:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered empty.	(b) (4) Lauren Hewitt (b) (4)	23 Mar 2021 14:36:52

US3482023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:45:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'Yes (Y)'	(b) (4) Lauren Hewitt (b) (4)	23 Mar 2021 14:37:06

US3482023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:45:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered '23 Mar 2021'	(b) (4) Lauren Hewitt (b) (4)	23 Mar 2021 14:37:06
	(b) (4)	

US3482023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:45:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered '08:43'	(b) (4) Lauren Hewitt (b) (4)	23 Mar 2021 14:37:06

US3482023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:45:43

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User entered '23 Mar 2021 08:43'	System	23 Mar 2021 14:37:06

US3482023

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'Yes (Y)'	(b) (4) Lauren Hewitt (b) (4)	23 Mar 2021 14:37:15

US3482023

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:45:58
User entered 'I'	System	23 Mar 2021 14:37:15

US3482023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:47:42

US3482023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:18
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:47:42

US3482023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:47:42

US3482023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:45:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:47:42

US3482023

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:47:47

US3482023

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:45:43

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 20:47:47

US3482023

Folder: Covid-19 Assessment 28 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:45:43

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:10:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:06:38

US3482023

Folder: Covid-19 Assessment 28 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:45:43

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:10:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered '09:46'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:06:38

US3482023

Folder: Covid-19 Assessment 28 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:45:43

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:10:23
User entered '28 Jan 2021 09:46'	System	11 Mar 2021 18:06:38

US3482023

Folder: Covid-19 Assessment 28 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:45:43

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:10:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'Safety Call (Safety Call)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:06:38

US3482023

Folder: Covid-19 Assessment 28 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:45:43

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:10:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:06:38

US3482023

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

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:44
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'Yes (Y)'	(b) (4) Lauren Hewitt (b) (4)	23 Mar 2021 14:31:57

US3482023

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

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:44
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered '23 Mar 2021'	(b) (4) Lauren Hewitt (b) (4)	23 Mar 2021 14:31:57

US3482023

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

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

[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 19:37:44
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'Clinic (Clinic)'	(b) (4) Lauren Hewitt (b) (4)	23 Mar 2021 14:31:57

US3482023

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

Form: Visit Date

Generated On: 09 Jun 2021 17:45:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:44
User entered 'UNBLND_DECIDE'	System	23 Mar 2021 14:31:57

US3482023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:45:43

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:44
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
Signature has been broken.	Mari Hart (b) (4)	12 Apr 2021 22:24:53
User entered empty; reason for change Per Query Resolution	Mari Hart (b) (4)	12 Apr 2021 22:24:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered '23 Mar 2021'	Lauren Hewitt (b) (4)	23 Mar 2021 14:34:12

US3482023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:45:43

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 19:37:44
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User closed query 'Per CDM: Subject was unblinded under A5 per data below, however Date of updated informed consent is provided. Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:15:49
Query 'Per CDM: Subject was unblinded under A5 per data below, however Date of updated informed consent is provided. Please review and reconcile.' answered with 'updated' (Site from DM).	Mari Hart (b) (4) (b) (4)	12 Apr 2021 22:25:02
Signature has been broken.	Mari Hart (b) (4) (b) (4)	12 Apr 2021 22:24:53
User entered '1' reason for change: Per Query Resolution	Mari Hart (b) (4) (b) (4)	12 Apr 2021 22:24:53
User opened query 'Per CDM: Subject was unblinded under A5 per data below, however Date of updated informed consent is provided. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 20:53:20
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	01 Apr 2021 22:28:55
User entered '0'	Lauren Hewitt (b) (4) (b) (4)	23 Mar 2021 14:34:12

US3482023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:45:43

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:44
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'Yes (Y)'	(b) (4) Lauren Hewitt (b) (4)	23 Mar 2021 14:34:12

US3482023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:45:43

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:44
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:08:21
User closed query 'Per CDM: Per sponsor review, Per IRT subject was unblinded under Amendment 5. Please review and update. ' (Site from DM).	(b) (4)	
Query 'Per CDM: Per sponsor review, Per IRT subject was unblinded under Amendment 5. Please review and update. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 09:52:39
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 17:56:56
User entered 'Amendment 5 (Amendment 5)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:56:34
User opened query 'Per CDM: Per sponsor review, Per IRT subject was unblinded under Amendment 5. Please review and update. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 17:23:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	
	Lauren Hewitt (b) (4)	23 Mar 2021 14:34:12
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 17:45:43

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:44
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 14:42:56
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'Participant was unblinded prior to EUA' (Site from System).	Lauren Hewitt (b) (4) (b) (4)	23 Mar 2021 14:36:19
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	23 Mar 2021 14:34:12
User entered '28 Dec 2020'	Lauren Hewitt (b) (4) (b) (4)	23 Mar 2021 14:34:12

US3482023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:45:43

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:44
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Lauren Hewitt (b) (4)	23 Mar 2021 14:34:12

US3482023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:45:43

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:44
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Lauren Hewitt (b) (4)	23 Mar 2021 14:34:12

US3482023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:45:43

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:44
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Lauren Hewitt (b) (4)	23 Mar 2021 14:34:12

US3482023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:45:43

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:44
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'No (N)'	(b) (4) Lauren Hewitt (b) (4)	23 Mar 2021 14:34:12

US3482023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:45:43

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:44
User entered empty.	System	23 Mar 2021 14:34:12

US3482023

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

Form: Unblinding

Generated On: 09 Jun 2021 17:45:43

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:44
User entered empty.	System	23 Mar 2021 14:34:12

US3482023

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:45:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:44
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'Yes (Y)'	(b) (4) Lauren Hewitt (b) (4)	23 Mar 2021 14:34:33

US3482023

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:45:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:44
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered '23 Mar 2021'	(b) (4) Lauren Hewitt (b) (4)	23 Mar 2021 14:34:33

US3482023

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:45:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:44
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered '08:43' reason for change: Data Entry Error	(b) (4)	
	Lauren Hewitt (b) (4)	23 Mar 2021 14:35:21
User entered '08:38'	(b) (4)	
	Lauren Hewitt (b) (4)	23 Mar 2021 14:34:33
	(b) (4)	

US3482023

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:45:43

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:44
User entered '23 Mar 2021 08:43'	System	23 Mar 2021 14:35:21
User entered '23 Mar 2021 08:38'	System	23 Mar 2021 14:34:33

US3482023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:45:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:44
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered 'Yes (Y)'	(b) (4) Lauren Hewitt (b) (4)	23 Mar 2021 14:35:14

US3482023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:45:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:44
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered '23 Mar 2021'	(b) (4) Lauren Hewitt (b) (4)	23 Mar 2021 14:35:14

US3482023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:45:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:44
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 22:28:55
User entered '08:38'	(b) (4) Lauren Hewitt (b) (4)	23 Mar 2021 14:35:14

US3482023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:45:43

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:44
User entered '23 Mar 2021 08:38'	System	23 Mar 2021 14:35:14

US3482023

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:45:43

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:31
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:58:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 20:45:34

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:34:26
User entered		
'USA-US106-2020-mRNA-1273-P301000003'	System	16 Nov 2020 22:34:22
User entered 'New'	(b) (4), (b) (6)	16 Nov 2020 22:34:22

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain upper, LLT: Epigastric pain - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 20:49:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 20:49:46
Data point term sent to Coder	System	13 Nov 2020 20:48:22
User entered 'Epigastric Pain'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered '4 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 20:48:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered '5 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered '4 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered '5 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 14:45:06
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' answered with 'updated' (Site from DM).	Michele McCullough (b) (4)	01 Dec 2020 21:31:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Michele McCullough (b) (4)	24 Nov 2020 22:11:05
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:19:41
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered 'Not Related (NOT RELATED)'	Michele McCullough	24 Nov 2020 22:11:05
reason for change: Data Entry Error	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

None

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 17:55:48
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 17:55:48
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 17:55:48
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 17:55:48
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
User closed query 'Per DM: ConProc is checked on AE of EPIGASTRIC PAIN; however, there is no matching indication given on ConProc eCRF. Please review and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 12:09:36
Query 'Per DM: ConProc is checked on AE of EPIGASTRIC PAIN; however, there is no matching indication given on ConProc eCRF. Please review and update as appropriate.' answered with 'He required an inpatient hospitalization. 06MAR2021 JCW' (Site from DM).	Joy Winters (b) (4) (b) (4)	06 Mar 2021 15:58:00
User opened query 'Per DM: ConProc is checked on AE of EPIGASTRIC PAIN; however, there is no matching indication given on ConProc eCRF. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 03:09:55
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 17:55:48
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 17:55:48
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	13 Nov 2020 20:48:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

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 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 20:48:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:10:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:35:49
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 15:58:52
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 15:58:49
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 15:58:47
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 15:58:44
User closed query 'Per DM CLR: Narrative indicates that Pain Medication was provided. However, there is no recorded ConMed treatment for this AE. Please review and update to record the corresponding pain medication as appropriate and update Other Action Taken. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 05:46:26
Query 'Per DM CLR: Narrative indicates that Pain Medication was provided. However, there is no recorded ConMed treatment for this AE. Please review and update to record the corresponding pain medication as appropriate and update Other Action Taken. Otherwise, clarify.' answered with 'pain medication added to con med eCRF' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 19:48:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'medical records, which include treatment given for event have been sent to Safety_Moderna@iqvia.com' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 19:42:37
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'medical records, which include all relevant laboratory and diagnostic test results have been emailed to Safety_Moderna@iqvia.com' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 19:42:08
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Records have been sent via email to Safety_Moderna@iqvia.com' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 19:41:03
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'history of known gallstone' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 14:05:14
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 19:12:46
User opened query 'Per DM CLR: Narrative indicates that Pain Medication was provided. However, there is no recorded ConMed treatment for this AE. Please review and update to record the corresponding pain medication as appropriate and update Other Action Taken. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 12:40:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 18:34:44
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 18:34:33
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 18:34:23
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 18:33:57
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 18:33:48
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	13 Nov 2020 20:56:53
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	13 Nov 2020 20:56:53
User entered '70 year old admitted on 11/04/20 and discharged 11/5/20 with epigastric pain likely due to gall stones. pain medication provided along with proton pump inhibitor with EDG planned as outpatient. SAE not related to study protocol.' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 20:56:53
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	13 Nov 2020 20:48:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 20:48:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 20:48:15

US3482023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:45:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 20:48:15

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:31
User closed query '(re-issued per clinical request) Per CDM Review: The participant has indicated that they have received facial cosmetic injections on the Cosmetic Injection_ Dermal Filler eDiary form. However, there are no concomitant medications or medical history terms that correspond to a dermal filler. Please review and clarify or reconcile' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 16:09:16
Query '(re-issued per clinical request) Per CDM Review: The participant has indicated that they have received facial cosmetic injections on the Cosmetic Injection_ Dermal Filler eDiary form. However, there are no concomitant medications or medical history terms that correspond to a dermal filler. Please review and clarify or reconcile' answered with 'Botox for cosmetic reasons' added to the medical history.' (Site from DM).	Amy Anderson (b) (4) (b) (4)	20 Apr 2021 15:03:31
User opened query '(re-issued per clinical request) Per CDM Review: The participant has indicated that they have received facial cosmetic injections on the Cosmetic Injection_ Dermal Filler eDiary form. However, there are no concomitant medications or medical history terms that correspond to a dermal filler. Please review and clarify or reconcile' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 18:16:56
User closed query 'Per CDM Review: The participant has indicated that they have received facial cosmetic injections on the Cosmetic Injection_ Dermal Filler eDiary form. However, there are no concomitant medications or medical history terms that correspond to a dermal filler. Please review and clarify or reconcile.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 18:16:44

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
Query 'Per CDM Review: The participant has indicated that they have received facial cosmetic injections on the Cosmetic Injection_ Dermal Filler eDiary form. However, there are no concomitant medications or medical history terms that correspond to a dermal filler. Please review and clarify or reconcile.' answered with 'Subject entered "yes" to ed diary facial cosmetic injections in error. Note is in source.' (Site from DM).	Mari Hart (b) (4) (b) (4)	19 Apr 2021 16:11:18
User opened query 'Per CDM Review: The participant has indicated that they have received facial cosmetic injections on the Cosmetic Injection_ Dermal Filler eDiary form. However, there are no concomitant medications or medical history terms that correspond to a dermal filler. Please review and clarify or reconcile.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 20:40:17
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 18:39:13
User closed query 'Per ETRTR: According to Narrative of SAE "EPIGASTRIC PAIN" medication was administered for this event. Please ensure medication is present in the Concomitant Medication and the Action taken for this event is also updated.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 18:39:11
Query 'Per ETRTR: According to Narrative of SAE "EPIGASTRIC PAIN" medication was administered for this event. Please ensure medication is present in the Concomitant Medication and the Action taken for this event is also updated.' answered with 'pain medication added to conmed eCRF' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 19:49:32
User opened query 'Per ETRTR: According to Narrative of SAE "EPIGASTRIC PAIN" medication was administered for this event. Please ensure medication is present in the Concomitant Medication and the Action taken for this event is also updated.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 14:20:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 18:57:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:45:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Aug 2020 19:00:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:00:39
Data point term sent to Coder	System	24 Aug 2020 18:59:17
User entered 'Losartan'	(b) (4), (b) (6)	24 Aug 2020 18:58:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:45:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User closed query 'Per DM CLR: Please review "Other Route" as there is an available option for "Intraocular" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 19:04:24
Query 'Per DM CLR: Please review "Other Route" as there is an available option for "Intraocular" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 14:21:26
User opened query 'Per DM CLR: Please review "Other Route" as there is an available option for "Intraocular" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 06:12:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 18:58:34

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:45:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Hypertension'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:58:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:45:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:17:46
	(b) (4)	
Signature has been broken.	Lauren Hewitt (b) (4)	02 Apr 2021 18:03:42
	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
	(b) (4)	
User entered '100'	(b) (4), (b) (6)	24 Aug 2020 18:58:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:45:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:58:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:45:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:58:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:45:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:58:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:45:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:58:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:58:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:45:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:58:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:45:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'un Feb 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:58:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:45:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:58:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:45:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:58:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:45:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:58:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:45:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:58:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:45:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 18:58:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 18:58:34

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 18:58:34

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:45:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: DULOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: CYMBALTA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Aug 2020 14:20:14
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 14:20:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: DULOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: CYMBALTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 14:19:45
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 14:19:45
Data point term sent to Coder	System	24 Aug 2020 19:01:24
User entered 'Cymbalta'	(b) (4), (b) (6)	24 Aug 2020 19:01:14

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:45:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
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 14:01:08
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 'matched with medical history' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 18:30:04
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)	24 Sep 2020 06:13:39
Query 'Per DM CLR: Please review "Other Route" as there is an available option for "Intraocular" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 06:13:24
User opened query 'Per DM CLR: Please review "Other Route" as there is an available option for "Intraocular" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 06:13:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 19:01:14

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:45:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'lateral iliotibial band syndrome'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:01:14

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:45:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '60'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:01:14

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:45:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:01:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:45:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:01:14

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:45:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:01:14

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:45:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:01:14

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:45:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:01:14

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:45:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:01:14

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:45:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:01:27
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 18:30:15
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 06:14:21
User entered 'un Jan 2015'	(b) (4), (b) (6)	24 Aug 2020 19:01:14

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:45:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:01:14

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:45:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:01:14

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:45:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:01:14

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:45:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:01:14

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:45:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:01:14

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:01:14

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 19:01:14

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:45:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Oct 2020 12:39:20
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 12:39:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: ERGOCALCIFEROL, PRODUCTSYNONYM: VIT D - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:04:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:04:40
Data point term sent to Coder	System	24 Aug 2020 19:03:37
User entered 'Vit D'	(b) (4), (b) (6)	24 Aug 2020 19:03:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:45:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:03:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:45:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'supplement'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:03:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:45:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '2500'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:03:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:45:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'IU (IU)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:03:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:45:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:03:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:45:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:03:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:45:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:03:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:45:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:03:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:45:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:03:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'un Jan 2009'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:03:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:45:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:03:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:45:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:03:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:45:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:03:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:45:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:03:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:45:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Aug 2020 19:03:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:03:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 19:03:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:45:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Aug 2020 19:05:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:05:45
Data point term sent to Coder	System	24 Aug 2020 19:04:39
User entered 'Zinc'	(b) (4), (b) (6)	24 Aug 2020 19:04:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:45:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:04:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:45:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Nutritional Supplement'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:04:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:45:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '50'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:04:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:45:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:04:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:45:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:04:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:45:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:04:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:45:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:04:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:45:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:04:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:45:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:04:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:45:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'un Mar 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:04:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:45:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:04:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:45:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:04:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:45:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:04:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:45:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:04:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:45:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:04:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:04:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 19:04:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:45:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Nov 2020 01:33:49
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 01:33:49
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA RHIZOME, PRODUCTSYNONYM: CURCUMIN TURMERIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:07:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:07:42
Data point term sent to Coder	System	24 Aug 2020 19:06:41
User entered 'Turmeric curcumin'	(b) (4), (b) (6)	24 Aug 2020 19:06:06

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:45:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:06:06

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:45:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'nutritional supplement'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:06:06

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:45:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '1.5'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:06:06

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:45:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'capsule (CAPSULE)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:06:06

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:45:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:06:06

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:45:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:06:06

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:45:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:06:06

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:45:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:06:06

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:45:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:06:06

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:45:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'un Jan 2019'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:06:06

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:45:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:06:06

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:45:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:06:06

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:45:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:06:06

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:45:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:06:06

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:45:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Aug 2020 19:06:06

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:06:06

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 19:06:06

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:45:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTI OBESITY PRODUCTS, PRODUCT: PHENTERMINE HYDROCHLORIDE, PRODUCTSYNONYM: ADIPEX-P - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 01:14:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 01:14:49
Data point term sent to Coder Coding entries removed.	System	03 Oct 2020 01:14:04
	(b) (4), (b) (6)	03 Oct 2020 01:13:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTI OBESITY PRODUCTS, PRODUCT: PHENTERMINE HYDROCHLORIDE, PRODUCTSYNONYM: ADIPEX-P - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 15:46:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 15:46:47
Data point term sent to Coder Coding entries removed.	System	08 Sep 2020 15:45:16
	(b) (4), (b) (6)	08 Sep 2020 15:45:00

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:45:43

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTI OBESITY PRODUCTS, PRODUCT: PHENTERMINE HYDROCHLORIDE, PRODUCTSYNONYM: ADIPEX-P - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 19:11:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 19:11:50
Data point term sent to Coder	System	24 Aug 2020 19:10:52
Data point term sent to Coder	System	24 Aug 2020 19:09:48
User entered 'Adipex-P'	(b) (4), (b) (6)	24 Aug 2020 19:09:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:45:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:09:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:45:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User closed query 'Per DM CLR: Please review and update to provide the medical condition that this medication was use for, rather than the action of the medication. Please update and ensure that there is a corresponding MH record to match the indication. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 10:33:29
Query 'Per DM CLR: Please review and update to provide the medical condition that this medication was use for, rather than the action of the medication. Please update and ensure that there is a corresponding MH record to match the indication. Otherwise, clarify.' answered with 'ordered to suppress appetite. Not linked to a medical condition' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 15:34:57
User opened query 'Per DM CLR: Please review and update to provide the medical condition that this medication was use for, rather than the action of the medication. Please update and ensure that there is a corresponding MH record to match the indication. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 15:21:03
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.)' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:01:56
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.)' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 01:13:50
User entered 'weight control' reason for change: Per Query Resolution	(b) (4), (b) (6)	03 Oct 2020 01:13:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:45:43

[Indication](#)

Audit	User	Time (GMT)
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.)' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 06:09:20
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 19:10:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 19:10:40
User entered 'appetite suppressant' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 19:10:40
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 19:09:47
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 19:09:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:45:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '37.5'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:09:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:45:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
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	24 Aug 2020 19:10:40
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 19:10:40
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 19:09:47
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 19:09:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:45:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:09:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:45:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
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	24 Aug 2020 19:10:40
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 19:10:40
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 19:09:47
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 19:09:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:45:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:09:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:45:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User closed query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	(b) (4) System	08 Sep 2020 15:45:00
User opened query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	24 Aug 2020 19:09:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	24 Aug 2020 19:09:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:45:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:45:00
User entered 'appetite suppressant'	(b) (4), (b) (6)	24 Aug 2020 19:09:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:45:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'un Jun 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:09:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:45:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:09:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:45:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:09:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:45:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '06 Jul 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:09:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:45:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:09:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:45:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:54
User entered '1'	System	24 Aug 2020 19:10:40
User entered empty.	System	24 Aug 2020 19:09:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:54
User entered '1'	System	24 Aug 2020 19:10:40
User entered empty.	System	24 Aug 2020 19:09:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:33:54
User entered '804 (804)'	System	24 Aug 2020 19:10:40
User entered empty.	System	24 Aug 2020 19:09:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:45:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	26 Aug 2020 06:10:39
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 06:10:39
Data point term sent to Coder	System	24 Aug 2020 19:14:07
User entered 'Bio complex 3 Probiotic'	(b) (4), (b) (6)	24 Aug 2020 19:13:33

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:45:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:13:33

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:45:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'nutritional supplement'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:13:33

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:45:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '2'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:13:33

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:45:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'capsule (CAPSULE)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:13:33

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:45:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:13:33

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:45:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:13:33

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:45:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:13:33

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:45:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:13:33

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:45:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:13:33

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'un UNK 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:13:33

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:45:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:13:33

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:45:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:13:33

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:45:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:13:33

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:45:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:13:33

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:45:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Aug 2020 19:13:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:13:33

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 19:13:33

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:45:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:55:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: FLUOROQUINOLONES, PRODUCT: BESIFLOXACIN HYDROCHLORIDE, PRODUCTSYNONYM: BESIVANCE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 04:02:43
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 04:02:43
Data point term sent to Coder	System	08 Dec 2020 15:30:26
Data point term sent to Coder	System	08 Dec 2020 15:26:22
Coding entries removed.	(b) (4), (b) (6)	08 Dec 2020 15:26:01
User entered 'BESIVANCE ophthalmic' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 15:26:01
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: FLUOROQUINOLONES, PRODUCT: BESIFLOXACIN HYDROCHLORIDE, PRODUCTSYNONYM: BESIVANCE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 15:25:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 15:25:04
Data point term sent to Coder	System	08 Dec 2020 15:24:21
Coding entries removed.	(b) (4), (b) (6)	08 Dec 2020 15:23:35
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: FLUOROQUINOLONES, PRODUCT: BESIFLOXACIN HYDROCHLORIDE, PRODUCTSYNONYM: BESIVANCE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 01:16:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:45:43

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	03 Oct 2020 01:16:49
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	03 Oct 2020 01:16:05
Coding entries removed.	(b) (4), (b) (6)	03 Oct 2020 01:15:07
User coded data point as ATC: SENSORY	Coder Import (b) (4)	24 Sep 2020 14:20:55
ORGANS, ATC: OPHTHALMOLOGICALS, ATC:	(b) (4)	
ANTIINFECTIVES, ATC:		
FLUOROQUINOLONES, PRODUCT:		
BESIFLOXACIN HYDROCHLORIDE,		
PRODUCTSYNONYM: BESIVANCE - version		
WHODrug-Global-B3\\202003.		
User coded data point as Term Coded data point by	Coder Import (b) (4)	24 Sep 2020 14:20:55
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	24 Sep 2020 14:19:33
Coding entries removed.	(b) (4), (b) (6)	24 Sep 2020 14:18:46
User coded data point as ATC: SENSORY	Coder Import (b) (4)	24 Aug 2020 19:19:40
ORGANS, ATC: OPHTHALMOLOGICALS, ATC:	(b) (4)	
ANTIINFECTIVES, ATC:		
FLUOROQUINOLONES, PRODUCT:		
BESIFLOXACIN HYDROCHLORIDE,		
PRODUCTSYNONYM: BESIVANCE - version		
WHODrug-Global-B3\\202003.		
User coded data point as Term Coded data point by	Coder Import (b) (4)	24 Aug 2020 19:19:40
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	24 Aug 2020 19:18:15
User entered 'Besivance'	(b) (4), (b) (6)	24 Aug 2020 19:17:25

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:45:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:55:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Dec 2020 15:23:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 19:17:25

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:45:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:55:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 07:29:53
User entered 'CATARACT SURGERY' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 15:29:40
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 15:25:47
User entered 'Post CATARACT SURGERY' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 15:23:35
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 15:21:19
Query 'Per DM CLR: Please review "Other Route" as there is an available option for "Intraocular" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 06:10:03
User opened query 'Per DM CLR: Please review "Other Route" as there is an available option for "Intraocular" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 06:09:49
User entered 'Cataract surgery'	(b) (4), (b) (6)	24 Aug 2020 19:17:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:45:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:55:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:17:25

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:45:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:55:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:17:25

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:45:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:55:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'drop'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:17:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:45:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:55:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:17:25

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:45:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:55:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:17:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:45:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:55:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 10:33:44
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'data is correct' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 15:25:43
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 15:21:44
User closed query 'Per DM CLR: Please review "Other Route" as there is an available option for "Intraocular" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 19:04:36
User closed query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	03 Oct 2020 01:15:07
Query 'Per DM CLR: Please review "Other Route" as there is an available option for "Intraocular" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 14:18:58
User opened query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	24 Sep 2020 14:18:46
User entered 'Intraocular (INTRAOCULAR)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 14:18:46
User opened query 'Per DM CLR: Please review "Other Route" as there is an available option for "Intraocular" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 06:11:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:45:43

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	24 Aug 2020 19:17:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:45:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:55:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Oct 2020 01:15:07
User entered 'ophthalmic'	(b) (4), (b) (6)	24 Aug 2020 19:17:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:45:43

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:55:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '06 Jul 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:17:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:45:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:55:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:17:25

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:45:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:55:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:17:25

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:45:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:55:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:17:25

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:45:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:55:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:17:25

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:45:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:55:01
User entered '2'	System	24 Aug 2020 19:17:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:55:01
User entered '1'	System	24 Aug 2020 19:17:25

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:55:01
User entered '804 (804)'	System	24 Aug 2020 19:17:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:45:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: ANTIINFLAMMATORY AGENTS, NON-STEROIDS, PRODUCT: BROMFENAC SODIUM, PRODUCTSYNONYM: PROLENSA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 15:31:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 15:31:07
Data point term sent to Coder	System	08 Dec 2020 15:30:26
Data point term sent to Coder	System	08 Dec 2020 15:28:23
Coding entries removed.	(b) (4), (b) (6)	08 Dec 2020 15:28:23
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: ANTIINFLAMMATORY AGENTS, NON-STEROIDS, PRODUCT: BROMFENAC SODIUM, PRODUCTSYNONYM: PROLENSA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 01:16:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 01:16:49
Data point term sent to Coder	System	03 Oct 2020 01:16:06
Coding entries removed.	(b) (4), (b) (6)	03 Oct 2020 01:15:36
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: ANTIINFLAMMATORY AGENTS, NON-STEROIDS, PRODUCT: BROMFENAC SODIUM, PRODUCTSYNONYM: PROLENSA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 13:48:44
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 13:48:44
Data point term sent to Coder	System	24 Sep 2020 14:20:43

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:45:43

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	(b) (4), (b) (6)	24 Sep 2020 14:20:13
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: ANTIINFLAMMATORY AGENTS, NON-STEROIDS, PRODUCT: BROMFENAC SODIUM, PRODUCTSYNONYM: PROLENSA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 06:59:43
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 06:59:43
Data point term sent to Coder	System	24 Aug 2020 19:21:24
User entered 'Prolensa'	(b) (4), (b) (6)	24 Aug 2020 19:21:17

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:45:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:21:17

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:45:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User closed query 'Per DM CLR: Please review and update to provide the medical condition that this medication was use for, rather than surgery/rpocedure. Please update and ensure that there is a corresponding MH record to match the indication. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 07:31:06
User entered 'CATARACT SURGERY' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 15:30:08
Query 'Per DM CLR: Please review and update to provide the medical condition that this medication was use for, rather than surgery/rpocedure. Please update and ensure that there is a corresponding MH record to match the indication. Otherwise, clarify.' answered with 'taken to reduce eye swelling after surgery' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 15:29:09
User entered 'Post CATARACT SURGERY' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 15:28:23
User opened query 'Per DM CLR: Please review and update to provide the medical condition that this medication was use for, rather than surgery/rpocedure. Please update and ensure that there is a corresponding MH record to match the indication. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 15:23:20
User entered 'Cataract surgery'	(b) (4), (b) (6)	24 Aug 2020 19:21:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:45:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:21:17

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:45:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:21:17

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:45:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'drop'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:21:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:45:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:21:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:45:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:21:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:45:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 10:33:57
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'data correct' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 15:28:06
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 15:23:27
User closed query 'Per DM CLR: Please review "Other Route" as there is an available option for "Intraocular" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 19:04:51
User closed query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	03 Oct 2020 01:15:36
Query 'Per DM CLR: Please review "Other Route" as there is an available option for "Intraocular" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 14:20:21
User opened query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	24 Sep 2020 14:20:13
User entered 'Intraocular (INTRAOCULAR)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 14:20:13
User opened query 'Per DM CLR: Please review "Other Route" as there is an available option for "Intraocular" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 06:11:40

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:45:43

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	24 Aug 2020 19:21:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:45:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Oct 2020 01:15:36
User entered 'ophthalmic'	(b) (4), (b) (6)	24 Aug 2020 19:21:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:45:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '16 Jul 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:21:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:45:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:21:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:45:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:21:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:45:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:21:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:45:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:21:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:45:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:31
User entered '1'	System	24 Aug 2020 19:21:17

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:31
User entered '1'	System	24 Aug 2020 19:21:17

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:47:31
User entered '804 (804)'	System	24 Aug 2020 19:21:17

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:45:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:12:56
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: LOTEPREDNOL ETABONATE, PRODUCTSYNONYM: LOTEMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 15:24:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 15:24:01
Data point term sent to Coder Coding entries removed.	System	08 Dec 2020 15:23:19
	(b) (4), (b) (6)	08 Dec 2020 15:22:47
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: LOTEPREDNOL ETABONATE, PRODUCTSYNONYM: LOTEMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 15:18:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 15:18:02
Data point term sent to Coder Coding entries removed.	System	08 Dec 2020 15:17:13
	(b) (4), (b) (6)	08 Dec 2020 15:16:17
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: LOTEPREDNOL ETABONATE, PRODUCTSYNONYM: LOTEMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 01:16:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 01:16:50
Data point term sent to Coder	System	03 Oct 2020 01:16:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:45:43

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	(b) (4), (b) (6)	03 Oct 2020 01:15:59
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: LOTEPREDNOL ETABONATE, PRODUCTSYNONYM: LOTEMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 14:22:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 14:22:48
Data point term sent to Coder	System	24 Sep 2020 14:21:44
Coding entries removed.	(b) (4), (b) (6)	24 Sep 2020 14:20:53
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: LOTEPREDNOL ETABONATE, PRODUCTSYNONYM: LOTEMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:28:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:28:46
Data point term sent to Coder	System	24 Aug 2020 19:27:42
User entered 'Lotemax'	(b) (4), (b) (6)	24 Aug 2020 19:27:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:45:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:12:56
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:27:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:45:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:12:56
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 07:32:03
' (Site from DM).		
User entered 'Post cataract surgery' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 15:22:47
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	08 Dec 2020 15:18:37
' answered with 'Updated' (Site from DM).		
User entered 'CATARACT' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 15:16:17
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	12 Nov 2020 15:22:55
' (Site from DM).		
User entered 'Cataract Surgery'	(b) (4), (b) (6)	24 Aug 2020 19:27:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:45:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:12:56
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:27:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:45:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:12:56
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
Query 'Per DM CLR: Please review "Other Route" as there is an available option for "Intraocular" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 06:12:00
User opened query 'Per DM CLR: Please review "Other Route" as there is an available option for "Intraocular" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 06:11:54
User entered 'Other (OTHER)'	(b) (4), (b) (6)	24 Aug 2020 19:27:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:45:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:12:56
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Drop'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:27:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:45:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:12:56
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'three times daily (TID)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:27:54
User entered 'other (OTHER)'	(b) (4), (b) (6)	24 Aug 2020 19:27:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:45:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:12:56
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User closed query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	(b) (4) System	24 Aug 2020 19:27:54
User opened query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	24 Aug 2020 19:27:31
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 19:27:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:45:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:12:56
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User closed query 'Per DM CLR: Please review "Other Route" as there is an available option for "Intraocular" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 19:05:04
User closed query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	03 Oct 2020 01:15:59
Query 'Per DM CLR: Please review "Other Route" as there is an available option for "Intraocular" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 14:21:00
User opened query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	24 Sep 2020 14:20:53
User entered 'Intraocular (INTRAOCULAR)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 14:20:53
User opened query 'Per DM CLR: Please review "Other Route" as there is an available option for "Intraocular" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 06:12:09
User entered 'Other (OTHER)'	(b) (4), (b) (6)	24 Aug 2020 19:27:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:45:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:12:56
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Oct 2020 01:15:59
User entered 'Ophthalmic'	(b) (4), (b) (6)	24 Aug 2020 19:27:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:45:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:12:56
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '30 Jul 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:27:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:45:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:12:56
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:27:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:45:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:12:56
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:27:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:45:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:12:56
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:27:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:45:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:12:56
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:27:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:45:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:12:56
User entered '3'	System	24 Aug 2020 19:27:54
User entered empty.	System	24 Aug 2020 19:27:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:12:56
User entered '1'	System	24 Aug 2020 19:27:54
User entered empty.	System	24 Aug 2020 19:27:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:12:56
User entered '804 (804)'	System	24 Aug 2020 19:27:54
User entered empty.	System	24 Aug 2020 19:27:31

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:45:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
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)	24 Aug 2020 19:33:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:33:15
Data point term sent to Coder	System	24 Aug 2020 19:31:56
User entered 'Multivitamin'	(b) (4), (b) (6)	24 Aug 2020 19:31:24

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:45:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 07:32:12
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 16:02:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 16:02:01
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 15:23:09
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 19:31:24

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:45:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'nutritional supplement'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:31:24

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:45:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '1'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:31:24

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:45:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'tablet (TABLET)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Oct 2020 01:17:21
User entered 'Other (OTHER)'	(b) (4), (b) (6)	24 Aug 2020 19:31:24

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:45:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:02:57
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 01:17:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Oct 2020 01:17:21
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 06:16:03
User entered 'pack'	(b) (4), (b) (6)	24 Aug 2020 19:31:24

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:45:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:31:24

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:45:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:31:24

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:45:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:31:24

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:45:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:31:24

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:45:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:31:24

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:45:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:31:24

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:45:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:31:24

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:45:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:31:24

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:45:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:31:24

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:45:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:31:24

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Aug 2020 19:31:24

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 19:31:24

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:45:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	26 Aug 2020 08:27:37
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 08:27:37
Data point term sent to Coder	System	24 Aug 2020 19:36:12
User entered 'Cololite'	(b) (4), (b) (6)	24 Aug 2020 19:35:13

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:45:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:35:13

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:45:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Nutritional supplement'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:35:13

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:45:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '1'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:35:13

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:45:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'capsule (CAPSULE)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:35:13

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:45:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:35:13

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:45:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:35:13

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:45:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:35:13

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:45:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:35:13

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:45:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:35:13

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:45:43

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

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'un Jun 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:35:13

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:45:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:35:13

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:45:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:35:13

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:45:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:35:13

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:45:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:35:13

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:45:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:35:13

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:35:13

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 19:35:13

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:45:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:09
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 21:45:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 21:45:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: HERBAL NOS;INOSITOL;PASSIFLORA INCARNATA, PRODUCTSYNONYM: ZEN SHOT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 14:36:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 14:36:56
Data point term sent to Coder	System	21 Oct 2020 14:36:10
User entered 'flu shot'	(b) (4), (b) (6)	21 Oct 2020 14:35:11

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:45:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:09
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:35:11

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:45:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:09
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'health maintenance'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:35:11

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:45:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:09
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:35:11

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:45:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:09
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:35:11

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:45:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:09
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'injection'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:35:11

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:45:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:09
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:35:11

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:45:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:09
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:35:11

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:45:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:09
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:35:11

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:45:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:09
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:35:11

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:45:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:09
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '11 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:35:11

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:45:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:09
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:35:11

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:45:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:09
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:35:11

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:45:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:09
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '11 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:35:11

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:45:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:09
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:35:11

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:45:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:09
User entered empty.	System	21 Oct 2020 14:35:11

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:09
User entered empty.	System	21 Oct 2020 14:35:11

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:42:09
User entered empty.	System	21 Oct 2020 14:35:11

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:45:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:01:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User closed query 'Per DM CLR: This Conmed is given for the AE#1. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:56:43
' (Site from DM).		
Query 'Per DM CLR: This Conmed is given for the AE#1. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.	(b) (4), (b) (6)	11 Feb 2021 17:57:12
' answered with 'updated' (Site from DM).		
User opened query 'Per DM CLR: This Conmed is given for the AE#1. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.	(b) (4), (b) (6)	30 Jan 2021 20:37:36
' (Site from DM).		
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 19:48:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 19:48:51
Data point term sent to Coder	System	10 Dec 2020 19:48:13
User entered 'dilaudid'	(b) (4), (b) (6)	10 Dec 2020 19:47:27

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:45:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:01:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:47:27

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:45:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:01:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'epigastric pain management'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:47:27

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:45:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:01:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '2'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:47:27

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:45:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:01:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:47:27

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:45:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:01:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:47:27

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:45:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:01:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:47:27

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:45:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:01:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'every four hours' reason for change:	(b) (4)	
Data Entry Error	Hollie Macenczak (b) (4)	05 Jan 2021 23:06:47
User entered 'every four hourse'	(b) (4), (b) (6)	10 Dec 2020 19:47:27

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:45:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:01:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:47:27

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:45:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:01:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:47:27

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:45:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:01:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '4 Nov 2020'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:47:27

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:45:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:01:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:47:27

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:45:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:01:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:47:27

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:45:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:01:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '5 Nov 2020'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:47:27

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:45:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:01:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:47:27

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:45:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:01:02
User entered empty.	System	10 Dec 2020 19:47:27

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:01:02
User entered empty.	System	10 Dec 2020 19:47:27

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:01:02
User entered empty.	System	10 Dec 2020 19:47:27

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:45:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 22:31:08
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 22:31:08
Data point term sent to Coder	System	20 Jan 2021 19:19:45
User closed query 'For coding purposes, the reported trade name can be referenced with different formulations in the standard coding dictionary. Please enter the active ingredient(s) in parenthesis after drug name and please make your changes to the reported term.' (Site from System).	System	20 Jan 2021 19:19:30
Query 'For coding purposes, the reported trade name can be referenced with different formulations in the standard coding dictionary. Please enter the active ingredient(s) in parenthesis after drug name and please make your changes to the reported term.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	20 Jan 2021 19:19:30
User entered 'PROTONIX(pantoprazole)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 19:19:22
User opened query 'For coding purposes, the reported trade name can be referenced with different formulations in the standard coding dictionary. Please enter the active ingredient(s) in parenthesis after drug name and please make your changes to the reported term.' (Site from System).	Coder Import (b) (4)	06 Jan 2021 15:27:41
Data point term sent to Coder	System	05 Jan 2021 23:08:18

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:45:43

Name of Medication

Audit	User	Time (GMT)
User entered 'protonix'	Hollie Macenczak (b) (4)	05 Jan 2021 23:07:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:45:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:07:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:45:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'epigastric pain management'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:07:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:45:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '40'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:07:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:45:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'mg (mg)'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:07:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:45:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:07:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:45:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'once daily (QD)'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:07:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:45:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:07:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:45:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Oral (ORAL)'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:07:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:45:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:07:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:45:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '04 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:07:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:45:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:07:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:45:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:07:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:45:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '05 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:07:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:45:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:07:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:45:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:18
User entered '1'	System	05 Jan 2021 23:07:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:18
User entered '1'	System	05 Jan 2021 23:07:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:18
User entered '804 (804)'	System	05 Jan 2021 23:07:47

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:45:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:20
User closed query 'Per CDM: Please inactivate the Con Med log #17. Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 01:26:09
Query 'Per CDM: Please inactivate the Con Med log #17. Thank you. ' answered with 'Con Med log # 17 was inactivated ' (Site from DM).	Lauren Hewitt (b) (4)	02 Apr 2021 18:04:35
User opened query 'Per CDM: Please inactivate the Con Med log #17. Thank you. ' (Site from DM).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 15:44:39
	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	(b) (4)	
	Coder Import (b) (4)	05 Jan 2021 23:09:32
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 23:09:32
	(b) (4)	
Data point term sent to Coder	System	05 Jan 2021 23:09:19
User entered 'enoxaparin'	Hollie Macenczak (b) (4)	05 Jan 2021 23:08:34

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:45:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:08:34

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:45:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'DVT prophylaxis'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:08:34

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:45:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '40'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:08:34

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:45:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'mg (mg)'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:08:34

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:45:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:08:34

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:45:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'once daily (QD)'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:08:34

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:45:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:08:34

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:45:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:08:34

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:45:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:08:34

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:45:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '4 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:08:34

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:45:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:08:34

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:45:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:08:34

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:45:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '5 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:08:34

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:45:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 23:08:34

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:45:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:20
User entered '1'	System	05 Jan 2021 23:08:34

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:20
User entered '1'	System	05 Jan 2021 23:08:34

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:21:20
User entered '804 (804)'	System	05 Jan 2021 23:08:34

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:45:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:18
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 20:47:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 20:47:41
Data point term sent to Coder	System	19 Apr 2021 20:47:02
User entered 'Estradiol'	(b) (4), (b) (6)	19 Apr 2021 20:46:55

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:45:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:46:55

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:45:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:18
User entered 'Hormone Replacement'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:46:55

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:45:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:18
User entered '0.5'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:46:55

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:45:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:46:55

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:45:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:46:55

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:45:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:46:55

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:45:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:46:55

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:45:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:46:55

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:45:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:46:55

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:45:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:18
User entered '01 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:46:55

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:45:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:18
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:46:55

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:45:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:46:55

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:45:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:46:55

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:45:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:46:55

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:45:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:46:55

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:46:55

US3482023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:45:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 20:46:55

US3482023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:45:43

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:31
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	18 Feb 2021 19:01:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 18:57:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 18:55:26

US3482023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:45:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '09 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 19:05:40
User entered '9 Feb 2021'	(b) (4), (b) (6)	18 Feb 2021 19:02:46

US3482023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:45:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'gallbladder removal'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:02:46

US3482023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:45:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:02:46

US3482023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:45:43

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:02:46

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered		
'USA-US106-2020-MRNA-1273-P301000003'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'Yes (Y)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'Yes (Y)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'Easton'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'Beshears'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 17:14:33
User entered 'US'	System	16 Nov 2020 22:35:58

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Feb 2021 16:52:37
User entered '3'	System	12 Feb 2021 16:06:55
User entered '2'	System	25 Nov 2020 17:14:45
User entered '1'	System	16 Nov 2020 22:35:58

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered		
'USA-US106-2020-MRNA-1273-P301000003'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'Yes (Y)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'Yes (Y)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'Easton'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'Beshears'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 17:14:33
User entered 'US'	System	16 Nov 2020 22:35:58

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Feb 2021 16:52:37
User entered '3'	System	12 Feb 2021 16:06:55
User entered '2'	System	25 Nov 2020 17:14:45
User entered '1'	System	16 Nov 2020 22:35:58

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:45:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
User entered '16/Nov/2020 22:35'	System	16 Nov 2020 22:35:58

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:45:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 17:14:33
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 22:35:58

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'USA-US106-2020-MRNA-1273-P301000003'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'Yes (Y)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'Yes (Y)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'Easton'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'Beshears'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 17:14:33
User entered 'US'	System	16 Nov 2020 22:35:58

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Feb 2021 16:52:37
User entered '3'	System	12 Feb 2021 16:06:55
User entered '2'	System	25 Nov 2020 17:14:45
User entered '1'	System	16 Nov 2020 22:35:58

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:45:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
User entered '25/Nov/2020 12:14'	System	25 Nov 2020 17:14:45

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:45:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:06:26
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 18:36:19
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 17:14:45

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered		
'USA-US106-2020-MRNA-1273-P301000003'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'Yes (Y)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'Yes (Y)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'Easton'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'Beshears'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 17:14:33
User entered 'US'	System	16 Nov 2020 22:35:58

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Feb 2021 16:52:37
User entered '3'	System	12 Feb 2021 16:06:55
User entered '2'	System	25 Nov 2020 17:14:45
User entered '1'	System	16 Nov 2020 22:35:58

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:45:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '12/Feb/2021 10:06'	(b) (4) System	12 Feb 2021 16:06:55

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:45:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 16:42:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:42:50
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 16:42:13
User entered 'I'	(b) (4), (b) (6)	12 Feb 2021 16:06:55

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered		
'USA-US106-2020-MRNA-1273-P301000003'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'Yes (Y)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'Yes (Y)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'No (N)'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'Easton'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 22:35:53
User entered 'Beshears'	System	16 Nov 2020 22:34:22

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 18:36:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 17:14:33
User entered 'US'	System	16 Nov 2020 22:35:58

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:45:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Feb 2021 16:52:37
User entered '3'	System	12 Feb 2021 16:06:55
User entered '2'	System	25 Nov 2020 17:14:45
User entered '1'	System	16 Nov 2020 22:35:58

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:45:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered '12/Feb/2021 10:52'	(b) (4) System	12 Feb 2021 16:52:37

US3482023

Folder: SAE USA-US106-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:45:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:18:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:52:37